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Pregnancy and lactation during anifrolumab treatment in systemic lupus erythematosus

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Dear Editor,

Systemic lupus erythematosus (SLE) is a chronic multisystem autoimmune disease that predominantly affects women of childbearing age.[1-3] Cutaneous involvement represents one of the most common clinical manifestations of SLE and may occur in acute, subacute, or chronic forms.[2-4] SLE disease activity can be assessed with the Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) and the severity of cutaneous disease activity using the Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI).[5] Management of mucocutaneous SLE during pregnancy and breastfeeding remains challenging. In recent years, novel targeted therapies such as anifrolumab, a monoclonal antibody directed against the type I interferon receptor, have shown efficacy in patients with active SLE, particularly in those with prominent mucocutaneous manifestations.[6]

We report the management of a 39-year-old woman followed during pregnancy in 2024-2025 at the High-Risk-Pregnancy Outpatient Clinic of San Raffaele Hospital, Milan, Italy.

The patient had a past medical history of SLE with articular, serological, and severe mucocutaneous involvement since 2018. Cutaneous manifestations included ulcerative mucositis, cutaneous rashes, discoid lupus lesions, photosensitivity and digital vasculitic lesions. Since disease onset, mucocutaneous manifestations were steroid-dependent and refractory to multiple conventional and biologic therapies. In December 2022, intravenous anifrolumab was started for active mucocutaneous disease (SLEDAI 8 and CLASI A27/D6), resulting in progressive clinical remission.

In July 2024, the patient presented at our High-Risk-Pregnancy Outpatient Clinic following a positive pregnancy test. The last anifrolumab infusion was administered on June 5, 2024. Due to a flare of mucocutaneous manifestations during early pregnancy, and following multidisciplinary discussion, it was decided, in agreement with the couple, to resume anifrolumab treatment after 13 weeks of gestation (WG). A total of 6 monthly anifrolumab infusions were administered during pregnancy, up to 30 WG. Written informed consent was obtained. Close fetal monitoring with serial ultrasound examinations demonstrated normal growth throughout pregnancy. Delivery was scheduled for January 29, 2025, at 38+3 WG and was performed by elective caesarean section. A healthy male infant was born with a birth weight appropriate for gestational age (3,010 g) and the perinatal period was uneventful. Neonatal evaluation, including vital parameters and electrocardiogram, was unremarkable. At 15 days of life, the infant showed normal growth with exclusive breastfeeding. In March 2025, the patient experienced a cutaneous flare (Figure 1) and anifrolumab therapy was restarted while breastfeeding was continued.

Serum protein electrophoresis performed after drug administration showed a subtle, non-quantifiable increase in the gamma region,[7] with weak kappa light chain restriction, consistent with circulating

drug, without evidence of a monoclonal pattern. Despite this finding, neonatal follow-up remained normal: no recurrent or severe infections and no adverse reactions to vaccinations. Routine immunizations were administered according to the recommended schedule, except for the rotavirus vaccine, which was postponed as a precaution because it is a live-attenuated vaccine. Electrocardiogram and growth parameters were normal. Immunological evaluation at 4, 6 and 12 months of age revealed normal complete blood count, apart from mild age-appropriate neutropenia. T-cell subsets ($CD4^+$, naïve $CD4^+$, and $CD8^+$) were slightly reduced compared with age-matched reference values but progressively increased over time without intervention. Lymphocyte proliferative responses to mitogens and tetanus toxoid were normal. Immunoglobulin levels and vaccine-specific antibody responses (hepatitis B and tetanus) were adequate. Autoimmune screening (antinuclear antibodies and anti-double-stranded DNA) was negative. The child started nursery school at 9 months of age and experienced only minor infectious episodes.

Pregnancy in patients with SLE is associated with an increased risk of disease flares, which may occur during gestation or in the postpartum period.[8,9] Although corticosteroids remain a cornerstone of therapy, prolonged or high-dose use may be associated with maternal and obstetric complications and may not provide adequate disease control in refractory cases.

In recent years, several targeted therapies have been introduced for the treatment of moderate-to-severe SLE, particularly in patients with prominent mucocutaneous disease. However, their safety profile during pregnancy and lactation remains poorly defined, and there is no consensus regarding their use in this setting.[10-12]

In this case, anifrolumab allowed adequate control of severe mucocutaneous manifestations during pregnancy without evidence of maternal, fetal or neonatal toxicity. Similar favorable outcomes have recently been reported in one case report and a small case series of three pregnancies exposed to anifrolumab.[13,14] Furthermore, in our case, longitudinal follow-up of the infant did not reveal clinically significant immunological impairment or increased susceptibility to infections.

This report suggests that in selected patients with severe refractory mucocutaneous SLE, targeted therapies such as anifrolumab may represent a potential therapeutic option during pregnancy and lactation when disease control cannot be achieved with conventional treatments.[15] Nevertheless, further studies and post-marketing data are needed to better define the safety of these agents during pregnancy and breastfeeding.

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Figure 1. Clinical evolution of mucocutaneous lupus manifestations before and after treatment with anifrolumab. **a**) Severe palmar involvement with erythematous and desquamative lesions; **b**) complete resolution of palmar lesions after treatment; **c**) active mucocutaneous disease with erythematous plaques and inflammatory lesions involving the malar area and upper chest; **d**) marked improvement of facial skin lesions after treatment; **e**) severe involvement of the oral mucosa; **f**) complete resolution of oral mucosa after treatment.