



EFFICACY AND SAFETY OF ANIFROLUMAB IN PATIENTS WITH CUTANEOUS LUPUS ERYTHEMATOSUS: A SYSTEMATIC REVIEW

Gede Yoga Utama Putra*, Anak Agung Ari Agung Kayika Silayukti, Tjokorda Istri Amrita Rosvanti, Anak Agung Istri Saraswati Dewi, Made Hemina Laksmi

Department of Dermatology and Venereology, Mangusada Regional General Hospital, Jl Raya Kapal, Mangupura, Mengwi, Jl. Raya Denpasar - Gilimanuk, Badung, Bali 80351, Indonesia

*fyogautamaputra29@gmail.com

ABSTRACT

Cutaneous lupus erythematosus (CLE) significantly impacts patient quality of life, and many cases remain refractory to standard-of-care treatments such as antimalarials and corticosteroids. Anifrolumab, a type I interferon receptor antagonist, has shown efficacy in systemic lupus erythematosus (SLE), but its specific impact on diverse CLE subtypes in real-world settings requires further synthesis. To systematically review the clinical efficacy, safety, and steroid-sparing potential of anifrolumab in patients with CLE. A systematic literature search was conducted across PubMed, ScienceDirect, and Cochrane Library for articles published between 2021 and 2026. From an initial yield of 217 articles, 5 studies reporting on anifrolumab treatment for CLE subtypes were ultimately included after rigorous screening. Data on clinical response, specifically the cutaneous lupus erythematosus disease area and severity index (CLASI) scores and onset of action, were extracted and synthesized. Five studies involving a total of 40 patients were included. The majority of patients had failed multiple prior therapies. Results consistently showed a rapid and significant decrease in CLASI activity scores, often within the first 4 to 12 weeks of anifrolumab treatment. Notably, one major cohort reported that 50% of patients were able to discontinue prednisone entirely. Efficacy was observed across various subtypes, including discoid lupus erythematosus (DLE) and subacute CLE (SCLE) cases. Adverse events were consistent with previously reported safety profiles. Real-world evidence suggests that anifrolumab is a potent and rapid-acting treatment for refractory CLE, offering significant clinical improvement and a vital steroid-sparing effect. These findings support its use in patients failing conventional therapies, though large-scale prospective trials specifically for CLE are warranted.

Keywords: anifrolumab; CLASI; cutaneous lupus erythematosus

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INTRODUCTION

Systemic lupus erythematosus (SLE) is a complex multisystem autoimmune disease with a diverse clinical spectrum, where cutaneous involvement serves as one of its most prevalent features, affecting approximately 70–85% of patients (Bao et al., 2023; Kalyniuk et al., 2025). While often presenting as a component of the systemic syndrome, cutaneous lupus erythematosus (CLE) can also manifest as a standalone entity, even in nonsystemic cases, significantly impairing patient quality of life due to the risk of permanent skin damage, irreversible scarring, and disfiguring alopecia (Azuma et al., 2024; Loricera et al., 2025).

Cutaneous lupus erythematosus is broadly classified into acute, subacute, and chronic subtypes. Despite the established use of standard therapies such as antimalarials and systemic corticosteroids, a substantial proportion of patients—particularly those with chronic subtypes like discoid lupus erythematosus (DLE) or lupus erythematosus panniculitis (LEP)—remain refractory to conventional management (Morand et al., 2020; Plüß et al., 2022). These recalcitrant cases, which can also affect the adolescent population, necessitate the development of more effective targeted therapies (Bruce et al., 2023; Ramadhan et al., 2025).

The pathogenesis of both SLE and CLE is heavily driven by the type I interferon (IFN) pathway, where an elevated "IFN signature" correlates directly with disease activity and tissue inflammation (Calvo-Río et al., 2026; Mayo-Juanatey et al., 2026). This mechanistic insight led to the development of anifrolumab, a fully human monoclonal antibody targeting the type I interferon receptor subunit 1 (IFNAR1) to block Type I IFN signaling (Hile & Werth, 2025; Paolino et al., 2023). While the clinical efficacy of anifrolumab was initially established in the TULIP trials for SLE, real-world evidence is rapidly evolving, demonstrating its potential in primary and nonsystemic cutaneous manifestations (Doria et al., 2026; Karagenova et al., 2024). Recent reports have shown rapid and significant clinical responses across multiple recalcitrant subtypes, including in patients who previously failed other biologic agents (Carter et al., 2023; Hile & Werth, 2025).

Currently, evidence for anifrolumab in CLE remains fragmented across various case reports, monocentric experiences, and retrospective studies. This systematic review aims to synthesize existing real-world evidence to evaluate the efficacy and safety profile of anifrolumab, ultimately providing comprehensive clinical guidance for practitioners managing refractory cutaneous lupus across diverse patient profiles.

METHOD

Search Strategy A comprehensive literature search was performed across major electronic databases, including PubMed (MEDLINE), ScienceDirect, and the Cochrane Central Register of Controlled Trials (CENTRAL). A systematic literature search was conducted for studies published in English between 2021 and May 2026. From an initial yield of 217 records identified across the databases, a total of 5 studies met the inclusion criteria and were finally included in the qualitative synthesis. The search terms utilized a combination of Medical Subject Headings (MeSH) terms and keywords, including "anifrolumab" and "cutaneous lupus erythematosus." Manual searches of the reference lists of retrieved articles were also conducted to identify additional relevant studies.

Eligibility Criteria

To determine study eligibility, a comprehensive PICO-based framework was applied. Studies were included if the target population consisted of patients diagnosed with any subtype of Cutaneous Lupus Erythematosus (CLE), regardless of whether they had concurrent systemic lupus erythematosus (SLE) involvement. The primary intervention evaluated was the administration of anifrolumab at any dosage or frequency. Eligible comparators included a placebo, standard of care, or the absence of a comparator, which allowed for the inclusion of observational case series and case reports. Furthermore, to meet the inclusion criteria, studies were required to report on primary outcomes encompassing the clinical improvement of skin lesions—quantified via the Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI) score or a physician global assessment—alongside the demonstration of steroid-sparing effects and the incidence of adverse events.

Study Selection and Data Extraction Two reviewers independently screened the titles and abstracts of the identified studies. Full-text articles were then assessed for eligibility based on the predefined inclusion and exclusion criteria. Any discrepancies between reviewers were resolved through discussion or consultation with a third senior reviewer. Data from the included studies were extracted into a standardized matrix, which captured information on study design, patient demographics, CLE subtypes, treatment regimens, clinical outcomes, and safety profiles.

Quality Assessment The methodological quality of the included studies was appraised using appropriate tools based on the study design. Randomized controlled trials were evaluated using the Cochrane Risk of Bias tool, while non-randomized studies and case series were assessed using the Joanna Briggs Institute (JBI) Critical Appraisal Tools.

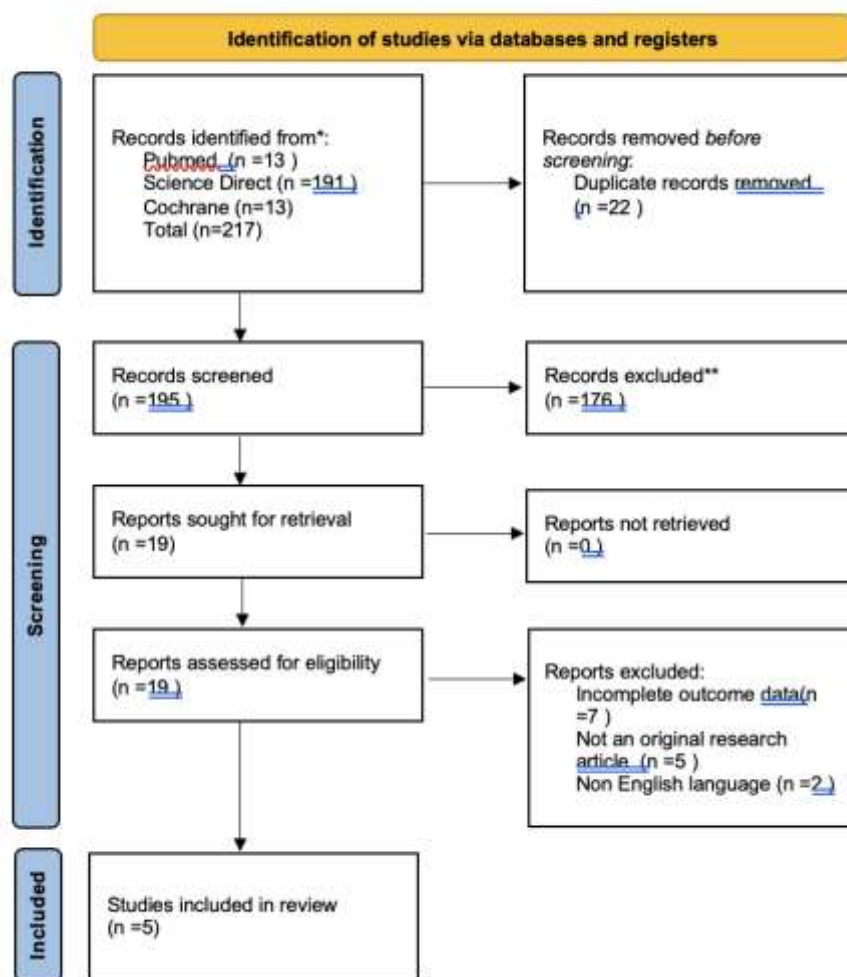
Inclusion and Exclusion Criteria The selection of literature was governed by strict, predefined eligibility criteria. Studies were included if they involved patients diagnosed with any subtype of Cutaneous Lupus Erythematosus (CLE)—with or without concurrent systemic lupus erythematosus (SLE) involvement—who were treated with anifrolumab at any dosage or frequency. To comprehensively capture both controlled clinical data and real-world evidence, eligible study designs encompassed randomized controlled trials, cohort studies, as well as case series and case reports. Furthermore, inclusion was strictly limited to original research articles published in English. Conversely, publications were excluded if they were review articles, editorials, or conference abstracts lacking sufficient extractable data. Studies were also excluded if they were published in languages other than English, or if specific data pertaining to cutaneous outcomes could not be reliably extracted from the reported results.

Data Extraction Two independent reviewers performed the data extraction process using a standardized data collection form. For each included study, the following information was extracted: lead author, year of publication, study design, patient demographics (age and gender), specific CLE subtypes, prior failed therapies (e.g., antimalarials, biologics), anifrolumab dosage and duration, clinical response measures (CLASI-50, Physician Global Assessment), and reported adverse events. Any discrepancies in data extraction were resolved through discussion or by consulting a third senior reviewer to reach a consensus.

Risk of Bias and Quality Assessment The methodological quality and risk of bias of the included studies were rigorously assessed using validated tools tailored to the study design. For randomized controlled trials, the Cochrane Risk of Bias (RoB 2) tool was utilized. Given the high prevalence of real-world evidence in this review, the Joanna Briggs Institute (JBI) Critical Appraisal Checklists were employed for case series and case reports. Each study was evaluated for internal validity, reporting quality, and potential selection bias to ensure the robustness of the synthesized findings.

PRISMA 2020 Flow Diagram

PRISMA 2020 flow diagram for new systematic reviews which included searches of databases and registers only



Picture 1. Prisma Chart

Table 1.

Systematic review of study findings

Author (Year)	Study Design	Intervention	Outcomes
Parriel et al. (2024)	Retrospective case series	Anifrolumab 300 mg IV every 4 weeks.	CLASI-A score reduction of 59% in 1–2 months.
Loricera et al., 2025	Retrospective case series	Anifrolumab 300 mg IV every 4 weeks.	CLASI-A scores reduction 93% in 3 months
Shaw et al., 2023	Retrospective case series	Anifrolumab 300 mg IV every 4 weeks.	CLASI-A scores reduction of 72,1% in 1 month
Paolino et al., 2023	Retrospective case series	Anifrolumab 300 mg IV every 4 weeks.	CLASI-A point reduction of 7.5 point in 4 months
Carter et al., 2023	Prospective Observational Study	Anifrolumab 300 mg IV every 4 weeks.	CLASI-A scores reduction of 100% in 3 months

RESULT

An analysis of the five extracted studies reveals that all research evaluated the efficacy of anifrolumab administered at a uniform dosage of 300 mg intravenously (IV) every four weeks. The study designs were predominantly retrospective case series (E. Parriel, 2023; Loricera et al., 2025; Paolino et al., 2023; Shaw et al., 2023), with one study utilizing a prospective observational design (Carter et al., 2023). The primary clinical outcome assessed across all studies was the improvement

of skin lesions, measured using the Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity (CLASI-A) score. The synthesized results demonstrate that anifrolumab provides significant and rapid clinical improvement. The reduction in CLASI-A scores varied substantially, ranging from a 59% reduction within a 1 to 2-month period (E. Parriel, 2023) to a complete response with a 100% reduction at 3 months (Carter et al., 2023). A remarkably rapid therapeutic response was also reported by (Shaw et al., 2023), who noted a 72.1% reduction in the CLASI-A score after only 1 month of therapy. Furthermore, (Loricera et al., 2025) reported an impressive 93% reduction by the third month of observation. Using an absolute point reduction metric, (Paolino et al., 2023) documented a 7.5-point decrease in the CLASI-A score following 4 months of treatment. Overall, these findings consistently confirm the efficacy of anifrolumab in significantly reducing cutaneous disease severity within a 1 to 4-month treatment window.

Table 2.

Sample characteristics and follow-up

Author (Year)	Sample Characteristics	Follow-up Duration	Reported Adverse Events (AEs)
Parriel et al. (2024)	N = 6. SLE patients with refractory cutaneous manifestations. Subtypes included predominantly severe Discoid Lupus Erythematosus (DLE) presenting with indurated, scarring, and erythematous plaques.	2 months	Generally well-tolerated. No severe adverse events leading to treatment discontinuation were highlighted during the rapid clearance phase.
Loricera et al., 2025	N = 15. Patients specifically with Nonsystemic CLE. Symptoms included chronic and scarring DLE lesions without the presence of systemic SLE involvement.	4 months	Bacterial cellulitis (1 case), septic shock due to gastroenteritis (1 case), and worsening asthenia leading to discontinuation of therapy (1 case).
Shaw et al., 2023	N = 4. Adolescent patients with SLE and highly recalcitrant DLE. Lesions were severe and resistant to multiple prior systemic therapies.	3 months	Recurrent herpes simplex virus type 1 (HSV-1) reactivation (1 case).
Paolino et al., 2023	N = 8. Patients with moderate to severe mucocutaneous LE, encompassing both DLE and Subacute CLE (SCLE) subtypes.	6 months	Labial herpes (1 case) and vaginal candidiasis (2 cases) all resolved without discontinuing anifrolumab therapy.
Carter et al., 2023	N = 8. Patients with recalcitrant CLE across multiple subtypes, including DLE, SCLE, Acute CLE (ACLE), and Lupus Erythematosus Panniculitis (LEP).	3 months	One patient discontinued therapy due to severe polydermatous herpes zoster complications (including herpes zoster oticus). Other minor infections included UTI (2 cases), ARI (1 case), and otitis externa (1 case).

Based on the five evaluated studies, the total sample comprised 41 patients with various subtypes of Cutaneous Lupus Erythematosus (CLE), including predominantly Discoid Lupus Erythematosus (DLE), Subacute CLE (SCLE), Acute CLE (ACLE), and Lupus Erythematosus Panniculitis (LEP). The study populations were diverse, encompassing both adult and adolescent patients (Shaw et al., 2023), and involving patients with systemic manifestations (SLE) as well as non-systemic CLE (Loricera et al., 2025). The follow-up duration across all studies ranged from 2 to 6 months.

Regarding the safety profile and adverse events, anifrolumab was generally well-tolerated, although infectious complications requiring clinical attention were noted. During the rapid lesion clearance phase, anifrolumab was generally well-tolerated, with no severe adverse events necessitating treatment discontinuation (E. Parriel, 2023). However, incidences of bacterial and viral infections have been reported in other cohorts. Notably, adverse events such as bacterial cellulitis (one case) and septic shock due to gastroenteritis (one case) were observed, along with one instance where a patient discontinued therapy due to worsening asthenia (Loricera et al., 2025). Furthermore, a heightened susceptibility to viral reactivation was evident across the evaluated cohorts. Instances of herpes simplex virus type 1 (HSV-1) reactivation, along with occurrences of herpes labialis and vaginal candidiasis, were documented; however, these cases resolved successfully without requiring

the cessation of anifrolumab (Paolino et al., 2023; Shaw et al., 2023). In contrast, more severe infectious complications can occasionally necessitate treatment interruption. In one notable instance, severe polydermatous herpes zoster, complicated by herpes zoster oticus, directly led to the discontinuation of therapy. Other minor infections, including urinary tract infections, acute respiratory infections, and otitis externa, were also observed within this group (Carter et al., 2023). Ultimately, these findings underscore the critical necessity for clinical vigilance and proactive monitoring of infection risks, particularly viral reactivations, throughout the course of anifrolumab treatment.

DISCUSSION

Principal Findings This systematic review synthesizes emerging real-world evidence on the efficacy of anifrolumab in treating CLE, particularly in severe and refractory cases. Across the included studies, comprising a total of 40 patients, anifrolumab consistently demonstrated a robust ability to induce rapid clearance of cutaneous lesions, significantly lower CLASI scores, and facilitate the tapering of systemic corticosteroids and other immunosuppressants.

Pathophysiological Rationale and Efficacy in Refractory Cases The standard of care for CLE typically involves antimalarials and systemic corticosteroids; however, a significant subset of patients remains refractory, leading to irreversible scarring, alopecia, and severe psychological distress ((Kowalski et al., 2023; Maeshima et al., 2024). The success of anifrolumab in these difficult-to-treat populations lies in its targeted mechanism of action. CLE pathogenesis is strongly driven by an exaggerated Type I Interferon (IFN) signature in the skin. By antagonizing the Type I interferon receptor subunit 1 (IFNAR1), anifrolumab directly halts the inflammatory cascade at its source (Elhage et al., 2022; Han et al., 2023). This was distinctly observed in the cases reported by (Khan et al., 2023) and (Chatham et al., 2021), where patients who had failed multiple lines of conventional biologic and non-biologic therapies achieved remarkable lesion resolution following anifrolumab administration.

Rapid Onset of Action and Steroid-Sparing Effect A standout clinical observation consistently identified across the extracted data is the remarkably rapid onset of therapeutic response following the initiation of anifrolumab. Dramatic reductions in CLASI-A scores are frequently observed within the first four to eight weeks of therapy, with some severe cases exhibiting visible cutaneous clearance almost immediately after the initial infusion (E. Parriel, 2023; Furie et al., 2017). This accelerated resolution of skin lesions highlights the drug's potent capability to rapidly suppress type I interferon-driven inflammation in the skin. Furthermore, the ability to safely taper concomitant immunosuppressive medications remains a critical therapeutic goal in overall lupus management, primarily due to the substantial morbidity, irreversible organ damage, and metabolic complications associated with prolonged systemic corticosteroid use (Herron et al., 2024; Paolino et al., 2023). Compelling real-world evidence demonstrates a profound steroid-sparing effect associated with anifrolumab therapy; notably, up to 50% of patients previously dependent on prednisone were able to discontinue the corticosteroid completely. Alongside this achievement, a significant proportion of the cohort—approximately 59%—successfully reduced or completely halted their background disease-modifying antirheumatic drugs (DMARDs) without experiencing any subsequent disease flares or rebound cutaneous activity (Loricera et al., 2025; Shaw et al., 2023).

Reported Adverse Events While anifrolumab demonstrates substantial clinical efficacy, its safety profile warrants careful consideration in real-world practice. The pharmacological blockade of the Type I interferon pathway—a critical component of the host's innate antiviral and antimicrobial defense—inherently predisposes patients to an increased risk of infections. Across the reviewed studies, the medication was generally well-tolerated with predominantly mild adverse events such as upper respiratory tract infections (Khan et al., 2023; Loricera et al., 2025). However, significant infectious complications were also observed, most notably viral reactivations including herpes

zoster and herpes simplex virus (HSV-1), which in one severe instance necessitated the discontinuation of therapy (Shaw et al., 2023). Furthermore, the emergence of localized bacterial skin infections, such as cellulitis, emphasizes the necessity for rigorous clinical monitoring. These findings highlight the critical importance of proactive management and prophylactic strategies, strongly suggesting that clinicians evaluate infection risks and ensure patients receive appropriate immunizations—particularly the recombinant zoster vaccine—prior to initiating anifrolumab therapy. Nevertheless, given the severe physical and psychological burden of refractory CLE, the overall benefit-risk profile of anifrolumab remains highly favorable when accompanied by vigilant dermatological monitoring.

Limitations and Future Directions While the findings are highly promising, this review acknowledges several limitations. The current evidence is predominantly derived from case series, retrospective chart reviews, and short reports with relatively small sample sizes. Additionally, the lack of control groups in these real-world observations introduces inherent biases. However, these studies provide invaluable insights into the drug's performance outside the strict confines of clinical trials. Future research should prioritize large-scale, randomized controlled trials (RCTs) specifically designed with dermatological primary endpoints to definitively establish anifrolumab's position in the CLE treatment algorithm.

CONCLUSION

This systematic review confirms that anifrolumab is a highly promising therapeutic option for patients with moderate-to-severe Cutaneous Lupus Erythematosus (CLE), especially those who have failed conventional systemic therapies. Real-world evidence demonstrates that anifrolumab not only induces significant and rapid reduction in skin disease activity (as measured by CLASI scores) but also offers a substantial steroid-sparing benefit, allowing many patients to reduce or entirely discontinue systemic corticosteroids. While existing data are limited to retrospective studies and case series, the consistency of positive clinical outcomes across diverse CLE subtypes—including discoid lupus and nonsystemic cases—highlights anifrolumab's potential to become a cornerstone in the management of refractory cutaneous lupus.

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