

ORIGINAL ARTICLE

A Retrospective Review of 22 patients on Anifrolumab in Refractory Cutaneous Lupus

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ABSTRACT

Cutaneous lupus erythematosus (CLE) is a heterogeneous disorder that can present alone as cutaneous disease or in conjunction with systemic lupus erythematosus (SLE). Despite CLE often being severe and worsening quality of life, there is still no FDA approved drug for CLE. Anifrolumab, a fully humanized IgG1κ monoclonal antibody, has become a drug of interest because of its significant skin improvement in the SLE trials. We performed a retrospective chart review of a cohort of twenty-four patients initiating anifrolumab infusion therapy from January to November 2022. Twenty-two patients were also identified as having CLE in addition to SLE. Chart review occurred up to August 21, 2023.

Of the twenty-two patients, thirteen (59%) were able to reduce or stop either prednisone or a disease-modifying antirheumatic drug (DMARD). Specifically, eight patients (36%) of the twenty-two completely stopped at least one DMARD. Notably sixteen patients (70%) started anifrolumab on prednisone with eight (50%) being able to discontinue prednisone completely. Seventeen (77%) of the twenty-two had improvement of skin lesions by resolution of rash, no flares since therapy initiation, repigmentation, hair regrowth, or decrease in erythema and scale. Two of the total twenty-four patients reviewed did not have clear evidence of cutaneous lupus although did have cutaneous disease likely related to SLE, therefore were not included in data analysis although are represented in Table 2. The decrease in disease burden, ability to decrease other therapies, and overall tolerability of anifrolumab makes it a promising therapy for those with CLE.

INTRODUCTION

Cutaneous lupus erythematosus (CLE) is best described as a heterogeneous disorder that can present alone as cutaneous disease or in conjunction with systemic lupus erythematosus (SLE). Though the morphology is variable, CLE can lead to disfiguring scars, atrophy, and alopecia.^{1,2} Skin disease burden correlates with

worsening emotional health within quality-of-life studies, even in comparison to patients with known hypertension, congestive heart failure or myocardial infarction.³ There are currently no FDA-approved targeted treatments for the disease.^{2,4-6}

While the exact etiology of CLE is not fully understood, research has shown the key role of Type 1 interferon in the cascade of inflammatory cytokine synthesis, immune

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complex deposition, and subsequent complement activation leads to the cutaneous manifestation of lupus.⁷ Patients with moderate to severe presentations of discoid or subacute CLE have been found to have the highest levels of IFN-1, supporting the notion that type 1 interferon is a key component in the pathophysiology of CLE and skin related SLE.^{7,8}

Anifrolumab is a fully humanized IgG1κ monoclonal antibody that binds to the IFN-α/β/ω receptor (IFNAR), thus inhibiting subsequent signaling by all type I IFNs.^{6,9} Anifrolumab was approved by the US Food and Drug Administration in July 2021 for patients with active SLE disease.^{7,10-12} The studies also showed that there was significant improvement in the cutaneous activity in comparison to the placebo.^{1,13} Not only is anifrolumab a promising therapy for active SLE, its mechanism of action and evidence of reduction in cutaneous lesions makes it a point of interest for clinicians treating patients with refractory CLE.

To our knowledge there have only been seven articles published, ranging from case reports to case series, and two prospective studies that examined the efficacy of anifrolumab in the context of patients with CLE since its FDA approval in 2021. In all cases, disease significantly improved with softening of plaques, hair regrowth and, in a few instances, supplemental therapies were discontinued.^{7, 9,14-18} Notably, the two prospective studies demonstrated an improvement in patient reported quality of life in addition to a reduction in CLASI scores after anifrolumab therapy initiation.^{17,18} The largest reported cohort from the aforementioned articles was eleven patients.¹⁸

The other studies highlighted the improvement of skin burden with the goal of

emphasizing anifrolumab's efficacy in this patient population, with the two prospective studies quantifying this improvement using the CLASI scoring system. A few of the articles noted alteration or discontinuation of concurrent treatments after initiating therapy. However, to our knowledge no one has looked at the use of anifrolumab through the focused lens of de-escalation of other medications in a cohort of this size.^{7,15-18} In addition to characterizing cutaneous alterations in patients with CLE who are currently being treated with anifrolumab, we also sought to follow the changes in concurrent medications upon initiating therapy, with the goal of emphasizing the benefits of treating CLE patients with anifrolumab. Here we present a case series of 22 patients being treated for CLE with anifrolumab and their subsequent outcomes.

MATERIAL AND METHODS

This retrospective chart review was approved by the Institutional Review Board of the University of Alabama Birmingham (IRB_300010576). The cohort included 31 patients with refractory discoid or cutaneous lupus that were identified as initiating anifrolumab infusion therapy from January to November 2022. The sample was collected from a cohort treated by the Department of Dermatology and Rheumatology at the University of Alabama at Birmingham.

Thirty-one patients were identified through pharmacy staff. Upon further review, seven of the patient charts were excluded from data analysis as it was determined that these seven patients did not initiate therapy, resulting in review and analysis of a final cohort number of twenty-four. Two patients did not have documentation supporting a clear diagnosis of CLE, leaving twenty-two patients with skin disease consistent with



Figure 1. Patient response 1 month after first infusion. (A) Before (B) After.

CLE. These patients were further categorized as discoid lupus erythematosus (DLE) or subacute cutaneous lupus erythematosus (SCLE) if this information was available. Four of the CLE patients did not have detailed notes of their skin disease other than a history of a malar rash. Additional data collection included general patient demographics such as age, sex, race, diagnosis, and existing comorbidities, relevant immunosuppressants being taken at the start of infusions, the number and dose of such medications at initiation and then after 3 months, 6 months, and 9 months to 1 year after infusion therapy, status of skin lesions after infusion therapy, other previously failed therapies, and examination of images if available. Adverse effects were recorded. Improvement of skin lesions were identified by observing before and after images when applicable, use of physical exam findings

reported in the patient chart, and patient reported improvement of skin burden. The patient demonstrated in Figure 1 was contacted and gave written consent for use of photos.

RESULTS

In regard to skin burden, all twenty-two patients had notes of skin involvement prior to and during anifrolumab therapy. In this cohort, seventeen (77%) of them had noted improvement of skin lesions that was characterized by resolution of rash, no flares since therapy initiation, re-pigmentation, hair regrowth, or decrease in erythema and scale. A dramatic, although representative response, is demonstrated in **Figure 1**. One of the two patients not included had cutaneous disease documented as livedo

Table 1. Patient Demographics.

Patient code ID#	Age	Sex	Race and ethnicity	Diagnosis	Duration (years)
1	38	F	Black or African American	DLE	At least 15 years
2	36	F	Black or African American	DLE	At least 13 years
5	26	F	Black or African American	DLE	At least 13 years
6	67	F	Black or African American	DLE	At least 23 years
7	42	F	Asian	DLE	At least 23 years
14	46	F	Black or African American	DLE	At least 15 years
18	28	F	Black or African American	DLE	At least 11 years
22	57	F	Black or African American	DLE	At least 7 years
3	67	F	White	CLE, DM/SLE overlap	At least 5 years
9	49	F	White	CLE	At least 13 years
13	30	F	Hispanic or Latino	CLE	At least 16 years
15	33	F	Black or African American	CLE	At least 3 years
25	69	F	White	CLE	At least 6 years
26	42	F	White	CLE	At least 9 years
28	59	F	White	CLE	At least 6 years
31	38	F	White	CLE	At least 5 years
8	55	F	White	SCLE	at least 12 years
20	57	F	Black or African American	Tumid lupus, SCLE	At least 21 years
11	36	F	Black or African American	SLE w/ Malar Rash	At least 15 years
12	28	F	White	SLE w/ Malar Rash	At least 10 years
16	45	F	White	SLE w/ Malar Rash	At least 8 years

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17	48	F	White	SLE w/ Malar Rash	At least 25 years
23	44	F	White	SLE with Livedo Reticularis	At least 8 years
24	78	F	White	SLE with Photosensitivity	At least 21 years

Table 2. Characteristics of Patient Response Upon Initiating Anifrolumab Therapy.

Patient code ID#	Diagnosis	Prior therapies	Anifrolumab initiation date	Therapy at start of Anifrolumab	Therapy at 3 months	Therapy at 6 months	Therapy at 9-12 months	Skin Improvement (Y/N)	Notes and Adverse Events
1	DLE	Anifrolumab clinical trial, Colchicine, HCQ, MPA, MTX, OCS, Ustekinumab clinical trial, TCS, Thalidomide	1/22	HCQ, 1080mg MPA BID, OCS 20mg QOD, Thalidomide, TCS	HCQ, 1080mg MPA BID, OCS 10mg QOD, d/c Thalidomide, TCS	MPA 1080mg BID, d/c OCS, TCS	HCQ, MPA 720mg BID, d/c TCS	Y	None
2	DLE	Cyclophosphamide, Cyclosporine, Dapsone, HCQ, IVIG, MMF, MPA, MTX, OCS, Quinacrine, Rituximab, TCI, TCS	2/22	HCQ, IVIG, 720mg MPA BID, TCS, TCI	HCQ, IVIG, 720mg MPA BID, TCS, TCI	d/c HCQ, IVIG, 720mg MPA BID, TCI, TCS, d/c Rituximab	IVIG, 360mg MPA QD, TCI, TCS	Y	None
5	DLE	Anakinra, AZA, Cyclophosphamide, Etanercept, HCQ, IVIG, MMF, MTX, OCS, Rituximab, TCI, TCS	8/22	HCQ, OCS 5mg, TCI, TCS	No f/u	HCQ, OCS 5mg, TCI, TCS	No f/u	Y	None
6	DLE	AZA, HCQ, Leflunomide, MMF, MTX, OCS, Quinacrine, Rituximab, TCI, TCS	5/22	HCQ, Leflunomide, HCQ, TCS	HCQ, Leflunomide, HCQ, TCS	HCQ, Leflunomide, HCQ, TCS	No f/u	Y	None
7	DLE	Anifrolumab clinical trial, HCQ, MMF, MPA, MTX,	9/22	HCQ, MTX 20mg, MPA 720mg BID, OCS	No f/u	HCQ, d/c MTX, MPA 720mg BID, d/c	No f/u	Y	None

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		Anifrolumab trial, OCS		20mg, Voclosporin		OCS, Voclosporin			
14	DLE	Belimumab, HCQ, OCS, MTX	10/22	MTX 10mg, OCS 2.5mg	no 3mo f/u	MTX 10mg, OCS d/c	d/c MTX	Y	Patient flared when missed infusions
18 ^a	DLE	HCQ, MMF, MTX, OCS, Quinacrine, Rituximab, TCI, TCS	6/22	HCQ, OCS 10mg, TCI, TCS	Patient stopped HCQ, d/c OCS, d/c TCI/TCS	Restarted HCQ per Rheumatology	HCQ	Y	None
22	DLE	HCQ, Leflunomide, MTX	5/22	HCQ, TCI	HCQ, TCI	HCQ, TCI	HCQ, TCI	Y	None
3	CLE, DM/SLE overlap	AZA, HCQ, IVIG, MMF, MPA, MTX, OCS, TCS	4/22	HCQ, IVIG, MTX 15mg, MPA 720mg BID, OCS 20mg	HCQ, IVIG, MTX 15mg, MPA 720mg BID, OCS 10 mg	HCQ, d/c IVIG, MTX 15mg, MPA 360 mg BID, OCS 5mg	HCQ, d/c MPA, MTX 15mg, d/c OCS	Y	None
9	CLE	Belimumab, HCQ, Leflunomide, MTX, OCS	3/22	HCQ, Leflunomide, TCS	HCQ, Leflunomide, TCS	d/c Anifrolumab, restart Belimumab	N/A	N	Limited response
13	CLE	AZA, HCQ, MMF, MTX, Rituximab, TCS	9/22	HCQ, MMF 1000mg BID OCS 10mg, TCS	N/A	N/A	N/A	N	Stopped Anifrolumab (1 infusion) in the setting of new onset lupus nephritis
15	CLE	Belimumab, HCQ, MPA, MMF, OCS, TCS, TCI	9/22	HCQ, OCS 20mg, TCS, TCI	HCQ, OCS 10mg, TCS, TCI	No f/u	No f/u	Y	None
25	CLE	HCQ, MMF, Quinacrine, TCS	6/22	HCQ, MMF 750 mg QD, TCS, TCS	HCQ, d/c MMF	HCQ	No f/u	Y	None
26	CLE	HCQ, OCS	10/22	HCQ, OCS 10mg	HCQ, OCS 10mg	Patient elected to stop Anifrolumab (4 mo)	N/A	N	Inconsistent with infusions due to contraction of

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									influenza complicated by sinus infection
28	CLE	AZA, HCQ, MMF, MTX, Quinacrine, TCI, TCS	10/22	AZA 50mg QD, HCQ, MTX 15mg, TCI, TCS	1mo (after 2 infusions) d/c AZA , HCQ, MTX 15mg, TCI, TCS	HCQ, MTX 15mg, TCI, TCS	HCQ, MTX 7.5mg , TCI, TCS	Y	None
31	CLE	AZA, HCQ, Leflunomide, OCS	8/22	HCQ, Leflunomide 20mg, OCS 10mg	2mo f/u (3 infusions) HCQ, Leflunomide 20mg, d/c OCS	HCQ, Leflunomide 20 mg (missed Jan-Feb infusions)	HCQ, Leflunomide 20 mg, OCS 15mg	N	Patient flared when missed infusions
8	SCLE	AZA, Dapsone, HCQ, IVIG, MTX, MMF, MPA, OCS, Quinacrine, Thalidomide, Lenalidomide, TCI, TCS	11/22	HCQ, IVIG, OCS 5-10mg, TCS, TCI	N/A	N/A	N/A	N	Infusion Reaction ^a
20	SCLE, Tumpid Lupus	HCQ, Dapsone, Leflunomide, MMF, MPA, MTX, TCS	4/22	HCQ, OCS 5mg, TCS	no 3mo f/u	HCQ, d/c OCS	HCQ	Y	None
11	SLE w/ Malar Rash	Abatacept trial, AZA, Belimumab, HCQ, Leflunomide, MMF, MTX, OCS, TCS	4/22	HCQ, Leflunomide, OCS 20mg, TCS	HCQ, Leflunomide, OCS 15 mg, TCS	d/c HCQ, OCS increase to 20mg due to uveitis , Leflunomide, TCS	OCS back to 15 mg , Leflunomide, TCS	Y	Uveitis favored to be secondary to SLE. Limited documentation of skin disease. No flares.
12	SLE w/ Malar Rash	Colchicine, Belimumab, HCQ, Chloroquine, IVIG, MTX, OCS, TCS	5/22	HCQ, IVIG, OCS 10mg	HCQ, IVIG, OCS 5mg	HCQ, IVIG, OCS 5mg	HCQ, IVIG, OCS 5mg	Y	Initial improvement with flare at 10months
16	SLE w/ Malar Rash	Belimumab, HCQ,	9/22	Leflunomide, OCS 10mg	no 3mo f/u	Leflunomide, d/c OCS	Leflunomide	Y	Reported fatigue,

		Leflunomide, Quinacrine							
17	SLE w/ Malar Rash	Belimumab, HCQ, OCS, TCS	10/22	HCQ, OCS 5mg, TCS	HCQ, OCS 5mg, TCS	d/c Anifrolu mab, restart Belimum ab (4 mo)	N/A	Y	headache s, nausea Stopped secondary to dizziness, fatigue, headache s
23	SLE with Livedo Reticula ris	Belimumab, HCQ, Leflunomide, MTX, OCS	6/22	MTX	MTX	MTX	MTX	Y	Limited document ation of skin disease. No flares.
24	SLE with Photosen sitivity	Belimumab, HCQ, MTX, OCS	6/22	HCQ, OCS 10mg	HCQ, OCS to 9mg (2mo)	HCQ, OCS 7mg	HCQ, OCS 5mg	Y	None

Abbreviations: AZA= Azathioprine, HCQ= Hydroxychloroquine, MMF= Mycophenolate mofetil, MPA= Mycophenolic acid, MTX= methotrexate, OCS= oral corticosteroids, TCI= topical calcineurin, TCS= topical corticosteroids inhibitors, f/u= follow up, d/c= discontinued, mo= month. Therapies that do not have the dose explicitly stated in the table were not altered during treatment with anifrolumab. ^aPatient noted in Figure 1. ^bTried anifrolumab but had severe reaction to initial infusion with dyspnea and chest tightness, coughing, and vomiting. She received the initial infusion just a week following her last IVIG infusion. Currently does not wish to continue to anifrolumab therapy.

reticularis and the other as photosensitivity. Both of these patients were noted to have had their skin disease improve while on anifrolumab and are still included in **Table 2** although not in the data analysis. Eight of eight (100%) DLE patient had skin improvement.

Thirteen (59%) of the total were able to reduce or stop either prednisone or a disease-modifying antirheumatic drug (DMARD). Eight patients (36%) completely stopped a DMARD. Sixteen patients (70%) started anifrolumab on prednisone with eight of these patients (50%) being able to discontinue prednisone completely. Seventeen (77%) of the twenty-two had improvement of skin lesions by resolution of rash, no flares since therapy initiation, repigmentation, hair regrowth, or decrease in erythema and scale.

The general demographics of this patient population were characterized based on age,

sex, race and ethnicity, diagnosis, and existing SLE comorbidities which can be seen in **Table 1**. The average age of the population is 44.7 years, with the youngest patient being 28 years and the oldest being 78 years of age. Average duration of disease since diagnosis was 12.6 years, ranging from at least 3 years to at least 25 years of disease burden. All 24 affected individuals are female, with 12 (50%) identifying as white, 10 (42%) identifying as black, 1 (4%) identifying as Hispanic or Latino and 1 (4%) identifying as Asian.

DISCUSSION

The previously conducted studies demonstrated the clinical relevancy in treating CLE cases with anifrolumab, with the two prospective studies reporting both a pan-reduction and partial complete response when assessing the cohorts' CLASI activity scores in addition to reduction and often

resolution of disease activity.^{3,17,18} In addition to demonstrating a decrease in skin disease burden in our patient population, we also were able to capture the benefits of treatment with anifrolumab regarding decreasing, and in some cases, discontinuing of other concurrent therapies after 3 months, 6 months, and 1 year of treatment with anifrolumab. The adverse effects of being on long term immunomodulating therapy is well documented, with oral corticosteroid and other DMARD treatment attributing to a myriad of side effects. The number of patients able to reduce or stop both prednisone and DMARDs is a promising finding particularly in the context of disease and therapy refractory cases.

Additionally, anifrolumab therapy has been reported to be well tolerated in comparison to other therapies, with the most common adverse effects including herpes zoster infection, headache, upper respiratory infection, nasopharyngitis, and urinary tract infection.^{5,14,19} In this review, one patient had an adverse reaction to the initial infusion consisting of dyspnea, chest tightness, coughing, and vomiting. Therapy was initiated one week following her last IVIG infusion and eventually she opted not to continue with the anifrolumab therapy. One patient was inconsistent with their infusions due to contraction of influenza, which could possibly be attributed to anifrolumab though further details were not appreciated within the patient's chart. One other patient initiated anifrolumab through a clinical trial although discontinued therapy after a single treatment in the setting of new onset lupus nephritis and was subsequently switched to cyclophosphamide. Both of these cases were included in data analysis.

Limitations of this study mostly pertain to its size, retrospective nature, and patients are from one tertiary center; thus, we are unable

to draw any statistically significant conclusions. Characterizing disease burden was not entirely objective as descriptions of skin lesions varied between clinicians and images were not available for every case. The decision to include the two patients who discontinued anifrolumab therapy into the analysis had a notable impact on the reported outcomes.

The combined observation of decrease in disease burden, alteration of dose and number of other therapies, and overall tolerability of anifrolumab makes it a promising therapy for those with CLE. Most notably, the rapidity of onset, often as soon as the first two infusions, warrants further investigation of its use for patients who suffer from CLE.

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