Section: General Medicine

Original Research Article

CLINICAL SPECTRUM AND OUTCOMES OF SEVERE SYSTEMIC COMPLICATIONS IN SYSTEMIC LUPUS ERYTHEMATOSUS: A PROSPECTIVE OBSERVATIONAL STUDY FROM A TERTIARY CARE CENTER IN NORTHEAST INDIA

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ABSTRACT

Background: Systemic Lupus Erythematosus (SLE) is a chronic autoimmune disease known for its multisystem involvement. Early diagnosis and effective treatment of severe complications are critical for improving patient outcomes. The objective is to assess the clinical spectrum, treatment strategies, and short-term outcomes of SLE patients presenting with major systemic complications in a tertiary care hospital in Northeast India. **Materials and Methods:** A hospital-based prospective observational study was conducted involving 32 patients with SLE, enrolled from July 2024 to June 2025. Inclusion was based on ACR/EULAR 2019 criteria and the presence of one or more major systemic complications. Detailed demographic, clinical, biochemical, hematological, and immunological profiles were documented. Patients were followed for six months for therapeutic outcomes and complications. **Result:** Of the 32 patients, 90.6% were female with a mean age of 26.4 ± 7.6 years. Common complications included lupus flare (33.3%), lupus nephritis (26.6%), autoimmune hemolytic anemia (AIHA) (20%), pericarditis (20%), and neuropsychiatric lupus (6.6%). All patients were treated with corticosteroids and hydroxychloroquine. Cyclophosphamide and rituximab were used in lupus nephritis and steroid-refractory AIHA respectively. Two patient died due to complication associated lupus nephritis and lupus flare complicated with sepsis. Most patients showed significant clinical recovery by six weeks. **Conclusion:** Lupus flares and Lupus nephritis are among the most frequent and serious systemic complications in SLE. Early immunosuppression and standardized management protocols can significantly improve outcomes. This study adds valuable data from northeastern India region perspective.

INTRODUCTION

Systemic Lupus Erythematosus (SLE) is a chronic, relapsing-remitting autoimmune disease with a broad spectrum of clinical manifestations that can affect virtually every organ system, including the skin, kidneys, cardiovascular system, hematologic system, and central nervous system. The disease is characterized by the production of a variety of autoantibodies, immune complex deposition, and complement activation, leading to widespread inflammation and tissue damage.[1]

Globally, the prevalence of SLE varies significantly, ranging from 20 to 150 cases per 100,000 individuals, with higher rates observed among women of reproductive age and in certain ethnic groups such as African-Americans, Hispanics, and Asians. Western cohorts, such as the LUMINA and Euro-Lupus studies, have highlighted the burden of organ-threatening complications like lupus nephritis, neuropsychiatric lupus, and hematologic disorders. Despite advancements in immunosuppressive therapies and biologics, SLE continues to be associated with considerable morbidity and

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mortality, especially when diagnosis or treatment is delayed.[2,3]

In the Indian context, several studies, including those by Malaviya et al. and Rathi et al., have indicated that SLE patients often present with advanced disease and more severe systemic involvement compared to Western populations. This disparity may be due to factors such as delayed diagnosis, limited access to specialized care, socioeconomic barriers, and a higher prevalence of infectious complications. Lupus nephritis, autoimmune hemolytic anemia (AIHA), serositis, and neuropsychiatric symptoms are commonly reported complications, often contributing to hospitalization and mortality. The Indian scenario is further complicated by overlapping infections, lack of uniform treatment protocols, and variations in the availability of diagnostic tools such as renal biopsy and autoantibody panels.[4,5]

Given these challenges, the clinical approach to SLE in resource-limited settings like Northeast India requires contextual data to inform evidence-based interventions. The scarcity of region-specific epidemiological studies limits our understanding of the local disease burden, treatment responses, and patient outcomes.[6]

This prospective observational study, conducted in a tertiary care center in Northeast India, aims to bridge this gap by assessing the clinical spectrum, therapeutic interventions, and short-term outcomes in patients with SLE who present with major systemic complications. The findings are intended to contribute to the evolving body of literature and serve as a foundation for larger multicentric studies across the Indian subcontinent. Additionally, insights from this study may guide the development of region-specific treatment algorithms, improve early recognition of severe disease phenotypes, and support the integration of advanced therapies into national clinical guidelines.[7]

MATERIALS AND METHODS

Study Design and Duration: This was a prospective observational study carried out at the Department of Medicine, Agartala Government Medical College, Tripura, from July 2024 to June 2025.

Inclusion Criteria

- Age ≥ 18 years
- Diagnosis of SLE as per ACR/EULAR 2019 classification criteria
- Presence of at least one major systemic complication (renal, hematologic, cardiac, or neuropsychiatric)

Exclusion Criteria

- Overlap syndromes
- Pregnancy complicating SLE.
- Incomplete clinical records or loss to follow-up.
- Not given informed consent.

Data Collection: A structured proforma was used to collect data on:

- Demographics (age, sex, socio-economic status)
- Clinical features (fever, rash, arthralgia, polyserositis, neuropsychiatric symptoms)
- Laboratory investigations (CBC, LFT, KFT, ANA, anti-dsDNA, ESR, complement levels, urine analysis)
- Imaging: Chest X-ray, echocardiography, neuroimaging (if indicated)
- Treatment regimens
- Short-term outcomes and mortality within 6 months

Follow-Up: All patients were followed monthly for 6 months to assess for clinical improvement, resolution of symptoms, lab normalization and recurrence or new complication development.

RESULTS

Table 1: Baseline Characteristics of Study Population

Variable	Value
Total Patients	32
Female (%)	29 (90.6%)
Mean Age (years)	28.4 ± 7.6

Table 2: Clinical manifestations at Presentation in SLE Patients (n = 32)

System Involved	Manifestation	Frequency (n, %)
Constitutional	Fatigue, malaise, fever, anorexia, weight loss	28 (87.5%)
Hematological	Any hematologic abnormality	25 (78.1%)
	Anemia of chronic disease	21 (65.6%)
	Thrombocytopenia	14 (43.8%)
	Leukopenia	9 (28.1%)
	Lymphopenia	7 (21.9%)
	AIHA	6 (20%)
Cutaneous	Any skin manifestation	24 (75.0%)
	Malar rash	18 (56.3%)
	Discoid rash	12 (37.5%)
	Alopecia	15 (46.9%)
	Photosensitivity	7 (21.9%)
	Mucosal ulcer	20 (62.5%)

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Table 3: Autoantibody and Immunologic Profile of SLE Patients (n = 32)

Parameter	Estimated Frequency (n)	Percentage (%)
ANA-IFA Titer	32	100
- 1:80	10	31.3
- 1:160	9	28.1
- 1:320	8	25
- >1:640	5	15.6
Anti-dsDNA	25	78.1
Anti–phospholipid	11	34.4
Anti–Sm	14	43.8
Low Complement Levels	24	75
Direct Coombs Test +	13	40.6

Table 4: Distribution of Major Complications

Major Complication	Number of Patients	Percentage (%)
Lupus Flare	10	33.30%
Lupus Nephritis	8	26.60%
Autoimmune Hemolytic Anemia	6	25.00%
Pericarditis	5	20.00%
Catastrophic APS	1	3.10%
Neuropsychiatric Lupus	2	6.60%

Table 5: Treatment Modalities in the Study Population

Treatment	Indication	No. of Patients
Hydroxychloroquine + Steroids	All	32
Intravenous High-dose Steroids	Lupus Flare	10
Cyclophosphamide (Euro-Lupus protocol)	Lupus Nephritis	3
Mycophenolate Mofetil	Lupus Nephritis	5
Rituximab (375 mg/m²/week × 4)	Steroid-refractory AIHA	2
SSRIs + Antiepileptic	Neuropsychiatric Lupus	2
Colchicine + NSAIDs	Pericarditis	5
IVIG + Anticoagulation	Catastrophic APS	1

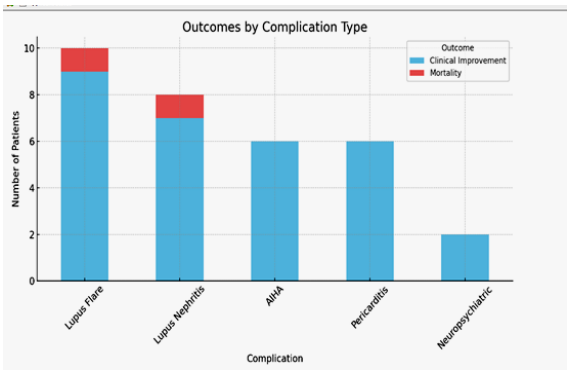

Figure 1: Outcomes by Complication Type

A total of 32 patients were included in the study. The majority were female (90.6%, n=29), while only three were male. The mean age of the study population was 28.4 ± 7.6 years.

Among the study cohort, the most common clinical manifestations were constitutional symptoms, observed in 28 patients (87.5%), predominantly presenting with fatigue, malaise, fever, anorexia, and weight loss. Hematological involvement was noted in 25 patients (78.1%), with anemia of chronic disease being the most frequent abnormality (65.6%), followed by thrombocytopenia (43.8%), leukopenia (28.1%), lymphopenia (21.9%), and autoimmune hemolytic anemia (20%). Cutaneous manifestations were present in 24 patients (75.0%), most commonly malar rash (56.3%) and mucosal ulcers (62.5%), while alopecia (46.9%), discoid rash (37.5%), and photosensitivity (21.9%) were also reported.

All patients in the study were ANA positive by IFA (100%), with titers ranging from 1:80 to >1:640. The most common titer was 1:80 (31.3%), followed by 1:160 (28.1%), 1:320 (25%), and >1:640 (15.6%). Anti-dsDNA antibodies were detected in 25 patients (78.1%), while anti-Sm antibodies and anti-phospholipid antibodies were present in 43.8% and 34.4% of cases, respectively. Low complement levels were observed in 24 patients (75%), and a positive direct Coombs test was noted in 13 patients (40.6%). Regarding disease-related complications, the most frequent was lupus flare, occurring in 10 patients (33.3%), followed by lupus nephritis in 8 patients (26.6%). Autoimmune hemolytic anemia was noted in 6 patients (25.0%), while pericarditis occurred in 5 patients (20.0%). Less commonly, neuropsychiatric lupus was observed in 2 patients (6.6%), and a single case of catastrophic antiphospholipid syndrome (3.1%) was documented.

All patients in the study received hydroxychloroquine in combination with corticosteroids (100%) as baseline therapy. Among those with complications, 10 patients (31.3%) required intravenous high-dose steroids for lupus flare. For lupus nephritis, 3 patients (9.4%) were treated with cyclophosphamide (Euro-Lupus protocol), while 5 patients (15.6%) received mycophenolate mofetil. Rituximab (375 mg/m²/week × 4) was administered in 2 patients (6.3%) with steroid-refractory autoimmune hemolytic anemia. Neuropsychiatric lupus was managed with SSRIs and antiepileptics in 2 patients (6.3%), whereas

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pericarditis was treated with colchicine and NSAIDs in 5 patients (15.6%). A single case of catastrophic APS (3.1%) required IVIG and anticoagulation.

DISCUSSION

This prospective observational study of 32 patients from a tertiary care center in North East India provides a valuable addition to the limited epidemiological and clinical data available from this region on systemic lupus erythematosus (SLE). The demographic profile of our study, with a marked female predominance (90.6%) and mean age of 28.4 ± 7.6 years, aligns with established data from other parts of India and global studies, reflecting the early-onset nature and female bias characteristic of SLE. For example, Mathur et al. (2022) from North India reported a female-to-male ratio of 19:1 and mean age of 23.3 years, while a tribal cohort from Ranchi also documented a similar female predominance (~90%) and mean age of 26.8 years. These consistent observations reinforce the high vulnerability of young Indian women to SLE across diverse geographic regions.

In terms of clinical manifestations, constitutional symptoms such as fatigue and fever were seen in 87.5% of our patients, similar to the 85–96% range reported in other Indian studies. Hematologic involvement was common in our cohort (78.1%), with anemia (65.6%) and thrombocytopenia (43.8%) being prominent. These figures are comparable to the North Indian data where anemia was reported in ~72%, thrombocytopenia in ~23%, and leukopenia in ~32%. However, our lymphopenia rate (21.9%) was slightly lower than that observed in some Indian cohorts, possibly reflecting differences in disease stage or treatment initiation timing.

Mucocutaneous involvement was frequent, observed in 75% of our patients, with malar rash in 56.3%, alopecia in 46.9%, and photosensitivity in 62.5%. These rates closely match those in Mathur's cohort (malar rash ~77.5%, alopecia ~60%) and are broadly consistent with reports from Jharkhand and southern India. Renal involvement in our study (26.6%) was on the lower side compared to Indian reports, which have shown lupus nephritis in 30–74% of patients, particularly among tribal and rural populations. This discrepancy may indicate milder disease, earlier detection, or genetic-environmental protective factors in the North Eastern population.

Globally, SLE prevalence varies, with higher rates in Afro-Caribbean and Hispanic populations and lower prevalence in South Asia (3.2/100,000 in India vs. 20–50/100,000 in Western cohorts). Our findings align with global literature indicating that non-European ancestry is associated with more aggressive disease, though our data suggest that the North Eastern Indian subset may have slightly less renal and neuropsychiatric involvement.

Serologically, 100% of patients were ANA-positive, and anti-dsDNA positivity was noted in 78.1%, comparable to other Indian and global cohorts. Anti-Sm antibody was detected in 43.8%, a relatively high proportion compared to other Indian studies (typically 29–40%), suggesting strong autoimmune activation. Hypocomplementemia (75%) and positive direct Coombs test (40.6%) further indicate significant immunologic activity.

Therapeutically, the majority of patients responded well to hydroxychloroquine and corticosteroids, with immunosuppressants like cyclophosphamide or mycophenolate used for lupus nephritis. Clinical improvement was seen in 93.3% of patients, and mortality was low (6.25%), primarily in those with nephritis and secondary sepsis—similar to outcomes reported from Indian tertiary care centers.

In North Eastern Indian SLE prospective study demonstrates a clinical and immunologic profile largely consistent with national data, though with slightly lower renal involvement. These findings underscore the need for more region-specific studies to capture the full spectrum of SLE across India's diverse populations.

Table 6: Comparative Analysis of SLE Cohorts – North East India vs Other Regions

Parameter	This Study (NE India, n=32)	North India (Mathur et al., 2022)	Ranchi Tribal Cohort	South India	Global Data
Female (%)	90.60%	~95% (19:1 ratio)	~90%	~92%	80–95%
Mean Age (years)	28.4 ± 7.6	23.3	26.8 ± 8.1	~30	25–40
Constitutional Symptoms	87.50%	>90%	96%	~85%	70–95%
Anemia	65.60%	72%	~88%	60–70%	40–75%
Leukopenia	28.10%	32%	54%	25–40%	20–40%
Lymphopenia	21.90%	54%	34%	~30%	15–40%
Thrombocytopenia	43.80%	23%	~40%	~25%	20–40%
Malar Rash	56.30%	77.50%	~60%	~65%	50–85%
Alopecia	46.90%	60%	~55%	~50%	30–60%
Photosensitivity	62.50%	70%	~66%	~55%	50–75%
Lupus Nephritis (%)	26.60%	~30%	56–74%	45–70%	30–60%
Neuropsychiatric Lupus	6.60%	~8–10%	~6%	10–15%	5–25%
Anti-dsDNA Positive	78.10%	57% (cutaneous-only); >80% systemic	84%	~70%	60–90%
Anti-Sm Positive	43.80%	~30–40%	~30%	29–49%	20–40%
ANA Positive	100%	100%	100%	100%	95–100%

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Low Complement (C3/C4)	75%	~70%	~66%	~60–70%	50–75%
Positive Coombs Test	40.60%	~30%	~35%	~30%	20–40%
Clinical Improvement Rate	93.30%	~90–95%	>90%	>90%	85–95%
Mortality (%)	6.25%	3–10%	~5–8%	4–9%	5–15%

CONCLUSION

Systemic complications are a major cause of morbidity and mortality in SLE patients. Our study highlights the importance of early diagnosis and institution of immunosuppressive therapy using evidence-based protocols. Timely intervention and multidisciplinary collaboration are essential in improving outcomes in resource-limited settings.

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