COLLEGE OF HEALTH SCIENCES AND MEDICINE

DEPARTMENT OF FAMILY AND COMMUNITY MEDICINE

PREVALENCE, RISK FACTORS, CLINICAL FEATURES & LABORATORY PROFILES OF SYSTEMIC LUPUS ERYTHEMATOSUS AT ADULT RHEUMATOLOGY FOLLOW UP CLINIC OF TIKUR ANBESSA SPECIALIZED HOSPITAL, ADDIS ABABA, ETHIOPIA.

A FINAL RESEARCH THESIS SUBMITTED TO THE DEPARTMENT OF FAMILY MEDICINE, SCHOOL OF MEDICINE, COLLEGE OF HEALTH SCIENCES, ADDIS ABABA UNIVERSITY IN PARTIAL FULFILLMENT OF THE REQUIREMENT FOR SPECIALTY CERTIFICATE OF FAMILY MEDICINE

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Approval by the board of examiners

This research thesis done by **Sara Yohannes Tesfaye** is accepted in its present form by the board of examiners as satisfying thesis requirement for specialty certificate of family medicine.

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ABSTRACT

Background: Systemic lupus erythematosus is a chronic autoimmune disorder that can affect multiple organ systems. It is more common in women of childbearing age and can be life-threatening. Its cause is not known and is diagnosed using one of three criteria. However, there is a lack of information about the prevalence and characteristics of SLE in native Sub-Saharan Africans.

Objectives: This study aimed to assess the prevalence, risk factors, clinical features and laboratory profiles of systemic lupus erythematosus among adult patients who visited rheumatology clinic at Tikur Anbessa Specialized Hospital of Addis Ababa, Ethiopia.

Methods: A retrospective chart review was conducted for patients aged 18 years or older who visited the adult rheumatology clinic of Tikur Anbessa Specialized Hospital in 2022. Data was extracted from the hospital's password-encrypted I-care system, then edited, cleaned, and compiled. Descriptive statistics were used to describe the study population, and associations between independent and dependent variables were expressed.

Results: Our study showed that 7.01% of 3650 patients had SLE. Male to female ratio was 1:16 & median age was 34.2 years. Cigarette smoking was a risk factor for SLE. Photo-sensitivity and cutaneous lupus were common. Comorbidities included cardiovascular diseases, lupus nephritis, neuro-psychiatric illnesses, pulmonary, ophthalmic, and gastrointestinal manifestations. ANA was positive in 98.8% of patients, and more than 95% were put on antimalarial agents and adjunct systemic corticosteroids.

Conclusion: The prevalence of systemic lupus erythematosus (SLE) in our area is 7.01%. Primary care physicians must have a good knowledge of the symptoms of SLE for early diagnosis, management, and prevention of complications.

Key words – Systemic Lupus Erythematosus, Prevalence, Adult, Rheumatology, Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia.

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ACRONYMS AND ABBREVIATIONS

ACR	American College of Rheumatology
ANA	Antinuclear antibodies
Anti Sm	Anti smith antibodies
BILAGI	British Isles Lupus Assessment Group
CBC	Complete Blood Cell Count
CDC	Center for Disease Control
dsDNA	Double Stranded Deoxyribonucleic Acid Antibodies
ACCP	Anticitrullinase peptidase antibodies
EULAR	European League Against Rheumatism
HGB	Hemoglobin
LVEF	Left Ventricular Ejection Fraction
NGO	Non Governmental Organization
RA	Rheumatoid Arthritis
SLE	Systemic Lupus Erythematosus
SLEDAI	Systemic Lupus Erythematosus Disease Activity Index
SLICC	Systemic Lupus International Collaborating Clinics
TASH	Tikur Anbessa Specialized Hospital
UK	United Kingdom
WBC	White Blood Cell
CDC	Center for disease control & prevention

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1. INTRODUCTION

1.1. Background

Systemic Lupus Erythematosus (SLE) is a multi-system chronic auto-immune disorder of unknown cause that is occasionally life-threatening[1]. It is characterized by the presence of antibodies to nuclear and cytoplasmic antigens and more than 90% of cases of SLE occur in women, frequently starting at childbearing age and 20% of patients with lupus are children[1-2]. The commonest groups of individuals affected are those in the age ranges of 14-64 years and kidney involvement is clinically apparent in about 50% of SLE patients and is a significant cause of morbidity and mortality[1]. Patients may exhibit a wide range of symptoms, signs, and laboratory results and their prognosis can vary depending on the severity of the disease and the organs that are affected [2]. SLE is diagnosed by the 2012 Systemic Lupus International Collaborating Clinics (SLICC) criteria (4 out of the 17 criteria); the 1997 American College of Rheumatology (ACR) criteria (4 out of the 11 criteria); or by the newly proposed and published in 2019 criteria of the ACR/European League Against Rheumatism (EULAR) (positive ANA ≥1:80 titer and score 10 or more points) [1-2].

Worldwide the prevalence of SLE varies and the overall prevalence rate of SLE ranges from 4.3 to 45.3 per 100,000 persons; with the overall incidence ranging from 0.9 to 3.1 per 100,000 persons per year[3]. It is more common in the Afro-Caribbean populations of Italy, Spain, Martinique, and the United Kingdom (UK) [4]. In the US, the center for Disease Control (CDC) sponsored five national lupus registries and the combined prevalence of SLE was 72.8 cases per 100,000 people [6]. The ACR classification requirements for SLE were met by an estimated 204,295 people in the US in 2018 [6]. SLE is frequently reported in Black people in the UK and the USA, but it is rarely reported in African populations, indicating that the disease may have both an environmental and a genetic foundation[4]. Moreover, Asians with SLE had higher rates of kidney involvement than White persons did, and cardiovascular involvement was a leading cause of death in Asians [4].

The epidemiology of SLE in Africa is largely unknown, and the widespread belief that SLE is extremely uncommon there continues[8]. However, recent studies indicate that many African patients are presenting with SLE nowadays[7-8]. The apparent low incidence rate in Africa may be

due to under-diagnosis brought on by poor access to healthcare, a lack of disease recognition in basic healthcare settings, restricted availability of diagnostic tools, and a shortage of specialized doctors [7].

Ethiopia has a huge population but relatively low healthcare spending and scarce healthcare resources, which has led to a high burden of infectious diseases and less focus on non-communicable diseases like SLE [29]. There are just only two national governmental rheumatology services at Tikur Anbessa Specialized Hospital (TASH) and Saint Paul Hospital Millennium Medical College (SPHMMC); apart from the only few private hospitals and clinics serving a large number of individuals across the country. Therefore, this research will be undergone in order to determine the prevalence and risk factors of SLE in Tikur Anbessa Specialized Hospital (TASH) of Addis Ababa, one of the two rheumatology public centers in the city. Hence, the results will eventually improve the treatment approach as well as management of those associated factors.

1.2. Statement of the Problem

SLE is a type of autoimmune disease in which the immune system attacks its own tissues, causing severe tissue damage and inflammation in the affected organs[2]. It has an effect on the blood vessels, brain, lungs, epidermis, and joints[1-2]. The affected region, which can range from the skin to various internal organs and present with a variety of symptoms, has a significant impact on the severity of the problems [2].

SLE is distinguished by flare-ups, which are periods of elevated disease activity followed by remissions[1]. According to research, 65-70% of SLE patients will experience at least one flare per year [3]. SLE flares are associated with increased annual medical expenses as the severity of the flare increases[3-4]. Because there is currently no cure for SLE, one of the primary therapeutic goals is to prevent disease flare-ups and progression[4]. Despite advances in our understanding of its origin, pathophysiology, and disease management, SLE continues to have a major impact on health-related quality of life and to be linked with severe comorbidity[5]. Heart attacks and related cardiovascular disorders, as well as significant microbiological infections, have emerged as leading causes of early mortality in persons with lupus, as death from renal disease has dropped recently [4].

SLE prevalence and severity vary by ethnic group and geographical region and according to estimates; the global prevalence of SLE is 5.14 per 100,000 person-years, with 0.40 million new cases diagnosed each year[4-5]. Male estimations were 1.53 per 100,000 person-years and 0.06 million persons per year, while female projections were 8.82 and 0.34 million, respectively[4]. Barbados, the United States, and Poland had the highest SLE incidence forecasts [4-5]. The highest frequency of SLE was discovered in Brazil, Barbados, and the United Arab Emirates [4-5].

Despite the fact that SLE affects more ethnic groups in low- and middle-income countries, these countries are underrepresented in epidemiological data on the disease[7]. Even though individuals with an African characteristic bear the greatest burden of SLE, the frequency and phenotype of SLE in native Sub-Saharan Africans have not been adequately explored [7]. SLE incidence and prevalence are currently on the rise across Africa[7-8]. According to several studies, the high prevalence of this illness in Africans may be related to their substantial sun exposure[10]. Evidence from a literature analysis reporting occasional cases of SLE in West and Central Africa up until the twentieth century reinforced the concept that SLE was a rare illness in Sub-Saharan Africa [7].

However, the small number of included research (mainly case reports and tiny case series) and the lack of incidence and prevalence data hampered the review's findings[5-7]. Recent clinical findings and the growth of African SLE research indicate that the myth of SLE scarcity in Sub-Saharan Africa is incorrect [7]. Ethiopia is a country in the Horn of Africa with a population of more than 120 million people[29]. Despite its vast population, Ethiopia has relatively low healthcare expenditure and limited healthcare resources, resulting in a high burden of infectious diseases and inadequate attention to non-communicable diseases such as SLE[31].

There are just two national governmental rheumatology services and a few private hospitals and clinics serving a large number of individuals across the country. The treatment of SLE in our set up includes short term NSAIDs, pulse steroids, antimalarial agents like chloroquine or immunosuppressive agents like cyclophosphamide, mycophenolatemofetil, or azathioprine. Patients are also usually linked to dermatology, psychiatric, renal and infectious disease clinics of TASH or Saint Paul Hospital Millennium Medical College (SPHMMC)[28-29]. As to our knowledge, SLE related researches in Ethiopia is very limited despite deep search for it and those available studies previously done were mainly focusing on the prevalence of associated consequences (such as neonatal lupus, lupus nephritis, and juvenile lupus) [28-30]. So this research

is planned to fill the research gaps about SLE by assessing the magnitude and associated risk factors of SLE. Therefore, a 1-year retrospective study at the adult rheumatology clinic of Tikur Anbessa Specialized Hospital in Addis Ababa, Ethiopia, was planned to fill research gaps about SLE by assessing the magnitude and associated variables of SLE.

1.3. Significance of the Study

This study gives information on the prevalence and risk factors for SLE at TASH's adult rheumatology clinic, which is a cross-sectional 1-year retrospective study, at adult rheumatology clinic of TASH, Addis Ababa, Ethiopia. Lupus is a chronic autoimmune illness that affects millions of individuals worldwide, with little knowledge on its prevalence in Ethiopia. Researchers can better comprehend the disease's burden in Ethiopia and establish suitable prevention and treatment methods by determining the prevalence of lupus in the country. The identification of the related components of lupus in Ethiopia will also help researchers understand the disease's origin and potential risk factors in this particular set up.

Such study can also persuade the Ministry of Health and regional health bureaus to pay attention to and develop public health policies and initiatives to avoid or lessen the disease's impact. Tertiary referral hospitals and other public rheumatologic care institutions, such as Saint Paul's Millennium Medical College and regional teaching health institutions, will benefit from this research as well, as it will help them understand lupus associated factors in our specific geographic location and its prevalence, allowing them to diagnose lupus early and effectively manage the anticipated complications.

Finally, lupus research can help improve diagnostic and therapeutic options for Ethiopian patients. Healthcare providers can better diagnose and treat lupus in Ethiopian patients if they understand the disease's distinctive characteristics in the nation. Overall, study on the frequency of lupus and its related characteristics in Ethiopia is critical for understanding the disease's effect, devising suitable preventative and treatment measures, and improving patient outcomes.

2. LITERATURE REVIEW

SLE is a complicated and heterogeneous disease with a wide range of clinical signs that can affect people of all ages, genders, and races. The global SLE prevalence and population afflicted were estimated to be 43.7/100,000 and 3.41 million, respectively[3]. The frequency of SLE in the general population is varied by area, ranging from 15.9/100,000 in southern Asia to 110.85/100,000 in tropical Latin America. The top four countries with the high SLE prevalence were the United Arab Emirates, Barbados, Cuba, and Brazil. Argentina, on the other hand, had the lowest prevalence [4]. Women were more likely than men to be affected by SLE in all international regions, and higher income regions had a higher prevalence of SLE. These income and population patterns might be attributed to better healthcare systems, easier access to experts, more comprehensive insurance records and higher levels of public awareness [5].

There are no epidemiological statistics on SLE for 79.8% of the world's nations. The Global Burden of condition group is the only source of global-based epidemiological data for SLE, but the condition is classed as "other musculoskeletal disorders" and there is still no detailed information on SLE epidemiological data internationally or for specific nations [5].

2.1. Global Overview

The Australian Lupus Registry shows that the prevalence of lupus in Australia is estimated to be around 20-60 cases per 100,000 people. On the contrary, recent data in Russia and Kahazakistan are lacking and old studies showed that prevalence of lupus is very low in these countries (Nasonov et al., 2013).

The prevalence of lupus in Europe is likely to be around 40-50 cases per 100,000 people, according to the European League Against Rheumatism. The Asia-Pacific Lupus Collaboration reports that the prevalence of lupus in Asia is estimated to be around 50-100 cases per 100,000 people, which is comparable to the Europe data. Moreover, the overall prevalence of SLE in Thrace, Turkey was 51.7/100,000 (O N Pamuk et al., 2015).

SLE is a complex disease that can present with a wide range of clinical manifestations, and there is evidence to suggest that the clinical features of SLE may differ between populations. For example, a study conducted by Yoo et al., (2017) found that Korean patients with SLE had a higher prevalence of neuropsychiatric manifestations compared to patients from other

populations. Similarly, a study conducted by Kaur et al., (2018) found that Indian patients with SLE had a higher prevalence of renal involvement compared to patients from other populations. This shows that race/ethnicity plays a major role as a risk factor for lupus.

According to the Lupus Foundation of America, it is estimated that 5 million people worldwide have lupus. At the regional level, the prevalence of SLE in the general population varied from 15.9/100 000 persons in southern Asia to 110.85/100 000 persons in tropical Latin America. For the general population, the top four countries with the highest estimates of SLE prevalence were the United Arab Emirates (166.92/100 000 persons), Barbados (163.31/100 000 persons), Cuba (149.9/100 000 persons) and Brazil (147.37/100 000 persons) (Tian et al., 2021).

Lupus Foundation of America estimated that around 1.5 million Americans (1 in 250) have lupus. On the other hand, the prevalence of lupus in Canada is estimated to be around 50,000-70,000 people (1 in 166), according to the Lupus Society of Canada. This finding is lower than that of the prevalence in the USA [6].

A systematic review of SLE among low and middle income countries showed that the SLE prevalence varied from 3.2-159/100,000 persons (Fatoye et al., 2022).

2.2. African Settings

There is a systematic review and meta-analysis of studies done among native sub Saharan Africans. The pooled prevalence of SLE among 28,575 Native sub-Saharan Africans seeking care in Internal Medicine and Rheumatology settings was 1.7%. There was a female predominance and the mean age at diagnosis was at the early fourth decade of life for most studies. The clinical manifestations of SLE were heterogeneous and the most common of them were musculoskeletal, dermatological and hematological (Essouma et al., 2020).

A cross sectional descriptive study done about the prevalence of SLE at Kenyatta national hospital over 14 years showed that out of a total of 166 patients diagnosed with SLE, 92.2% of the patients were females and 79.5% of the patients were females aged 18-60 years (Sube et al., 2020). In North Africa, a first ever study about genetic predisposition among SLE patients in Tunisia showed that familial predisposition is one of the risk factors for SLE. 10.67% of the studied lupus patients have proven family history of SLE (Chebbi et al., 2020).

The prevalence of SLE at two large hospitals in Uganda is 5.5% and the male-to-female ratio was 1:10. About 19.6% of the patients had SLE and RA overlap syndrome (Bongomin et al., 2020). On the contrary, A retrospective study done in Benin, West Africa showed that SLE seems rare (33 cases were diagnosed over 14 years). Similar study done in Burkinafaso stated that the prevalence of systemic lupus erythematosus among rheumatologic patients was 0.4% (Tiendrébéogo et al., 2022). Generally, in West Africa, the diagnosis is difficult because the clinical polymorphism by misdiagnosis and access serological profiles difficulty. However, the disease appears to be well controlled by treatment dominated by corticosteroids (Zomalheto et al., 2014). Data from an Egyptian cohort reported that among the 202 lupus patients studied, 91.1% were females and 8.9% patients were males. The mean age at the time of diagnosis was 26.71 ± 7.93 years. (Mohammed et al., 2022).

Other meta-analysis study assessed the prevalence of comorbidities and complications of lupus in native sub Saharan Africans and concluded that infections were the most common comorbidities (68.7%) followed by heart failure (33.3%), hypertension (19.6%), diabetes mellitus (18.7%) and stroke (6.8%) (Essouma & Nkeck et al., 2020). This was comparable with the study results of a research done in South Africa. The result showed that commonest comorbidities were hypertension (42%), serious infections (36.6%) and tuberculosis (18.8%), the latter two being significantly more common in the deceased group of patients. Other comorbidities like congestive cardiac failure, cerebrovascular disease and chronic kidney disease were also more common in these group. Both serious infections and TB were independent predictors of death (Greenstein, Makan & Tikly., 2019).

A systematic meta-analysis in Africa concluded that inadequate levels of serum vitamin D is significantly high in patients with SLE compared to healthy subjects, therefore, vitamin D supplementation with regular monitoring should be considered as part of their health management plans (Islam et al., 2019).

2.3. Ethiopian Situations

In Ethiopia, data about the prevalence of SLE are lacking. The prevalence of SLE as one of the chronic non infectious diseases of adults more than 20 years back was reported to be 81/100,000 (0.05%) at Tikur Anbessa Specialized Hospital over 4 years. This result was higher than the past prevalence reported in other African countries such as Nigeria and South Africa. Further and

updated researches are needed to confirm these findings and to determine the factors that may be contributing to the increased prevalence of SLE in this population (Tektonidou et al., 2019).

Another study done at Saint Paul Millennium Hospital and Medical College about the management practice and treatment outcomes of adult patients with lupus nephritis at renal clinic reported that 86.8% of lupus nephritis patients were female and 78% of them have a good prognosis (Hailu et al., 2022). A case of complete congenital heart block in a newborn associated with maternal SLE was seen at Myungsung Medical College, Addis Ababa, Ethiopia (Henok et al., 2023). This shows that although SLE is supposed to be rare or unreported in Ethiopia, its complications are rising and warrants new researches about its prevalence and associated factors to be done in developing African countries.

2.4. Conceptual Framework[10-11]

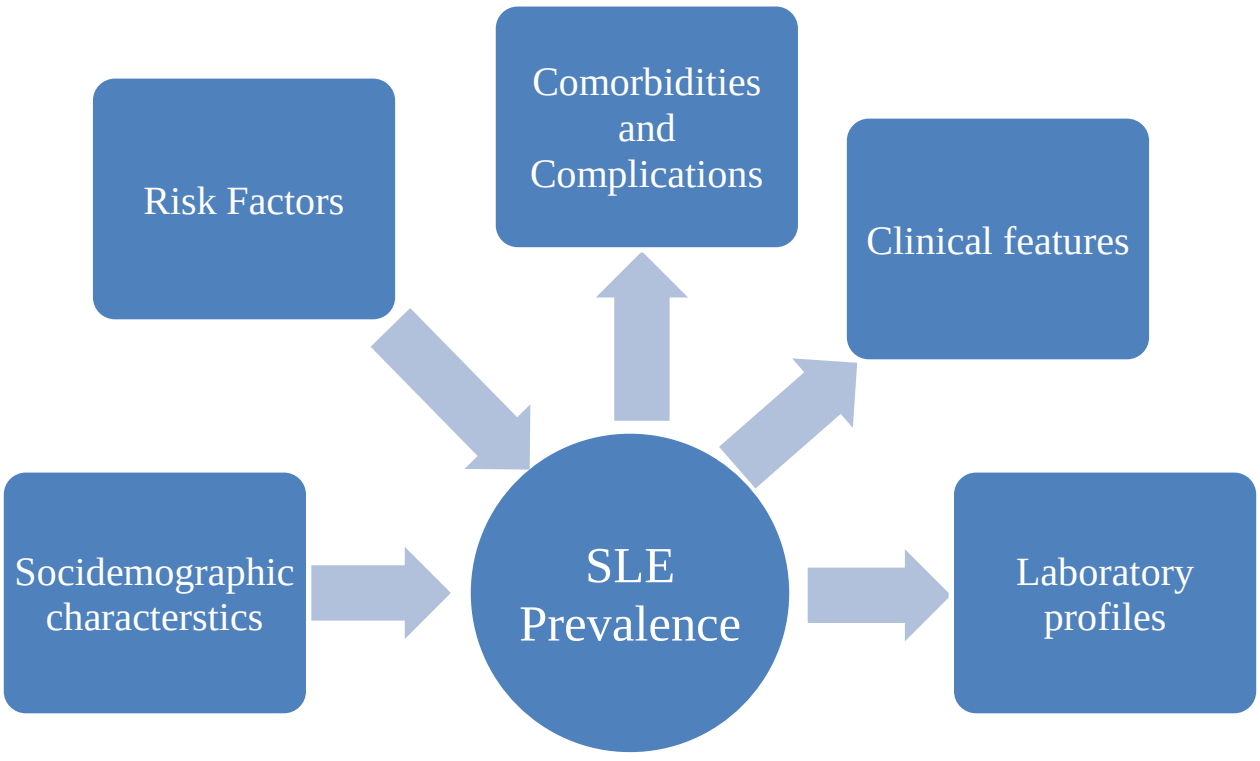


Figure 1: Researcher's own Conceptual Framework of the Study

3. STUDY OBJECTIVES

3.1. General Objective

The main objective of this study was to assess the prevalence and associated factors of systemic lupus erythematosus among adult patients visiting rheumatology clinic at Tikur Anbessa Specialized Hospital of Addis Ababa, Ethiopia, during the month of August, 2023 G.C.

3.2. Specific Objectives

The specific objectives of the study were:-

- ✓ To determine the prevalence of SLE in adult patients during the study period.
- ✓ To identify the associated risk factors of SLE in adult patients during the study period.
- ✓ To describe the SLE associated co-morbidities in adult patients during the study period.

4. METHODOLOGY

4.1. Study area

The study was conducted at the adult rheumatology clinic, internal medicine department of TASH (Addis Ababa University) which is located in Addis Ababa, Ethiopia. The rheumatology unit at TASH was established in 1998 G.C by the pioneer rheumatologist Dr. Zenebe Melaku and Sister Wubit. It has been giving teaching and residency training activities; in addition to the public services for patients of Addis Ababa and those referred from other regions of Ethiopia. Currently it is being mainly run by internists and internal medicine residents under supervision of two consultant Ethiopian rheumatologists who were previously sponsored by NGO (Rheumatology for all) for rheumatology fellowship training in South Africa[33].

4.2. Study Design and Period

A 1 year retrospective chart review was conducted in adult patients visiting rheumatology clinic in the month of August, 2023 G.C, at TASH of Addis Ababa, Ethiopia. The data was collected from the password encrypted I-care system of the hospital.

4.3. Population

4.3.1. Source Population

All adult patients who visited rheumatology clinic of TASH from January 01, 2022 to December 31, 2022 G.C were included.

4.3.2. Study Population

All adult patients who visited rheumatology clinic at TASH and fulfilled the inclusion criteria during the study period were included.

4.4. Eligibility criteria

4.4.1. Inclusion Criteria

- All charts of adult patients (aged greater than 18 years) who visited the study area during the study period.

4.4.2. Exclusion criteria

- Incomplete, empty or unfilled charts

4.5. Sample size determination

Since this study was a 1 year retrospective chart review, number of patients who are diagnosed as SLE by either the 2012 SLICC criteria, or the 1997 ACR criteria or the new 2019 ACR/EULAR criteria, are counted and studied. The total number of patients (N) who visited adult rheumatology clinic of Tikur Anbessa Specialized Hospital in the year of 2022 G.C. was 3650.

4.6. Sampling procedure

As described above, no sampling procedure is needed.

4.7. Variables of the Study

4.7.1. Dependent Variable

- SLE (Yes/No)

4.7.2. Independent Variables

- Socio-demographic Characteristics (Age, Gender, Religion, Marital status, Occupation, Duration of symptoms before diagnosis and Residence)
- Identified risk factors (Smoking, Occupational chemical exposure, Family history, Prior infection)
- Clinical features & co-morbidities (Cardiovascular disease, Thyroid disease, Allergic diseases, Obesity, Chronic kidney disease, Diabetes mellitus, Dermatologic disease, Psychiatric illness, Others)
- Laboratory features (CBC, ANA, Anti-dsDNA Abs, Serum Vitamin D level, Liver enzymes, Serum Creatinine, Lipid profile, coagulation profile)

4.8. Operational definitions

Definite SLE: is defined as after excluding alternative diagnoses, SLE is diagnosed in the patient who fulfills the 1997 ACR criteria, the 2012 SLICC criteria, or the 2019 EULAR/ACR criteria.

Probable SLE: are patients who do not fulfill the classification criteria for SLE but in whom we still diagnosing the disorder. These patients include those presenting with an inadequate number of ACR or SLICC criteria or those who have other SLE manifestations not included in either classification criteria or ANA negative lupus.

Possible SLE: is considered in individuals who have only one of the ACR/SLICC criteria, in addition to at least one or two of the other features like pneumonitis, myocarditis, abdominal vasculitis, Raynaud phenomenon, etc.…

Disease activity: This can be defined using various scales, such as the SLEDAI or the British Isles Lupus Assessment Group (BILAG) index.

Organ involvement: This can be defined as the presence of clinical or laboratory evidence of involvement of specific organs, such as the kidneys, lungs, or heart.

Cardiovascular Diseases: including Hypertension, Heart disease, Stroke, Peripheral vein thrombosis. (Based on the 2021 WHO definition)

4.9. Data Collection procedures and quality assurance

To gather the data, a data collection sheet/checklist from a similar previous studies done in West, East and South Africa was adopted after few amendments are done (as a data collecting tool). Training was given for staffs at adult rheumatology clinic on the process of data collection. Documents for persons who met the eligibility criteria were searched on I-care using data-gathering technologies and data was collected from the sampled and identified adult SLE patients during the study period. The checklist includes socio-demographic characteristics, identified risk factors, clinical features & comorbidities, and laboratory features. Before the data collection was started, data collecting format was cross matched with available information on electronic medical charts. Daily completeness of the data was cross checked and incomplete electronic medical records were reassessed. After full reassessment, incomplete electronic records information was discarded.

4.10. Data management and analysis

Data from the password-protected I-care system was retrieved and secured as an encrypted and password-protected electronic file and stored within the Addis Ababa College of Health Sciences firewall-protected SQL server. Furthermore, the data set and study information was backed up on a password-protected hard disk. All data are coded and entered into SPSS version 26.0 statistical software and MS Excel for analysis. Frequencies and proportions are computed for description of the study population. Descriptive statistics are expressed using means and frequency (proportions). It is presented in tables, graphs and charts. Associations between the independent

and dependent variables are expressed via Odds Ratio, P-value and the 95% using both simple and multiple logistic regression analyses.

4.11. Ethical considerations

Ethical clearance and written support letter was obtained from Research Ethics Review Committee of Department of Family Medicine, Addis Ababa University College of Health Sciences. The letter was given to head of adult rheumatology clinic of Tikur Anbessa Specialized Hospital. The inclusion of folder numbers was essential for the merging of episode and visit test data, but these were removed from the data set once the merge was completed. All analysis was done on anonymized data.

4.12. Dissemination of the result

This research paper is now being submitted to the family and community medicine department at Addis Ababa University, College of Health Sciences. The study's findings will be forwarded to the Ethiopian Ministry of Health. The findings will also be presented at various seminars, poster presentations (locally and internationally) and workshops, and may be published in peer review international scientific journals.

5. RESULTS OF THE STUDY

5.1. Sociodemographic characteristics of the patient

Out of the total 3650 patients who visited adult rheumatology clinic of Tikur Anbessa Specialized Hospital in the year of 2022, 256 patients were diagnosed with SLE **(prevalence of 7.01%).** Among these 256 SLE patients, 241 (94.1%) were females with male to female ratio of 1:16 and the mean age of the patients was 34.2 years (SD±12.27). Age of 65 or more years among the studied patients is 1.7x more observed in males than females (Odds ratio=1.7778 95% CI: 0.2140-14.7672). More than half of the patients, 156 (60.9%) were married and 196 (76.5%) were Christian in religion. The mean duration of symptoms before diagnosis was 6.5 months. One fourth of the patients, 73 (28.4%) are salaried employees, and 208 (81.4%) of the patients reside in urban setting.

Table 5.1 Sociodemographic characteristics of the patients (n=256)

Variables	**Categories**	**Frequency**	**Percentage**
Age in years	18-34	173	67.6%
	35-64	76	29.7%
	≥65	7	2.7%
Gender	Male	15	5.9%
	Female	241	94.1%
Marital status	Single	80	31.3%
	Married	156	60.9%
	Divorced	13	5.1%
	Widowed/widower	7	2.7%

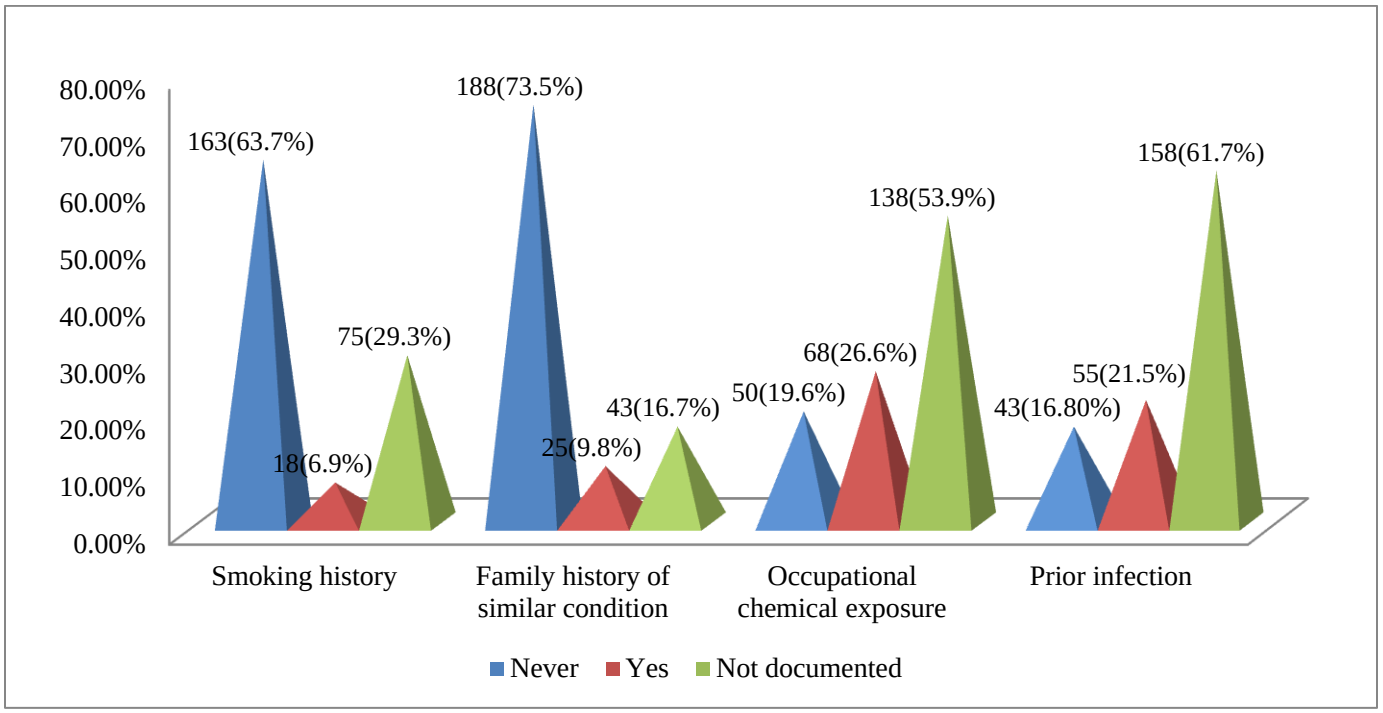
Religion	Christian	196	76.5%
	Muslim	55	21.6%
	Other	5	1.9%
Occupational status	Salaried employee	73	28.4%
	Merchant	55	21.7%
	Housewife	60	23.6%
	Student	28	10.8%
	Farmer	28	10.8%
	Other	12	4.7%
Residence area	Urban	208	81.4%
	Rural	48	18.6%
Duration of symptoms before diagnosis in years	<1 year	156	60.8%
	1-2 years	65	25.5%
	≥3 years	35	13.7%

(Other categories for religion include Jehovah's witnesses and for occupation include daily laborer & unemployed status).

5.2. Identified risk factors for SLE

Out of the 256 SLE patients, more than half of them, 163 (63.7%) had never smoked cigarettes and 25 (9.8%) of patients have family history of similar condition. Cigarrete smoking as a risk factor for SLE is 6x more common in males than females (Odds ratio= 6.2500 95% CI: 1.3272-29.4324). The occupational chemical exposure status of 138 patients (53.9%) and the presence of prior infection of 158 patients (61.7%) were not documented on the electronic medical records of the patients. The results of the identified risk factors are displayed on the following bar chart.

Figure 5.2 Identified risk factors for SLE (n=256)



5.3. Clinical features of SLE patients

Among the studied SLE patients, more than 90% of the patients had constitutional symptoms like fever (n=236, 92.2%), joint pain (n=244, 95.3%) and fatigue (n=240, 93.8%). Photosensitivity was present in 163 (63.7%) of patients and chronic cutaneous lupus with discoid subtype in 121 (47.3%) was more common than the acute cutaneous lupus like malar rash 88 (34.3%). About one third of patients, 93 (36.3%) had oral ulcer.

Table 5.3 Clinical features of the patients (n=256)

Variables	Categories	Frequency	Percentages
Fever	Yes	236	92.2%

Muco-cutaneous involvement	Photosensitivity	163	63.7%
	Malar rash	88	34.3%
	Discoid lupus	121	47.3%
	Oral ulcers	93	36.3%
	Others	12	4.7 %
Joint pain	Yes	244	95.3%
Fatigue	Yes	240	93.8%

Others category for muco-cutaneous involvement include other forms of cutaneous lupus & alopecia.

5.4. Complications & comorbidities among SLE patients

The overall prevalence of cardiovascular diseases among the 256 SLE patients was 41.8% (n=107), with hypertension being the most common 23.8% (n=61). The heart diseases in these patients were pericardial disease (n=6, 2.3%), left ventricular hypertrophy (n=13, 5.1%) and coronary artery disease (n=5, 1.9%). 11 patients (4.3%) had ischemic stroke and 4 patients (1.6%) had hemorrhagic stroke. About one fifth of the patients (n=54, 21.1%) had biopsy confirmed lupus nephritis; and 52 patients (20.3%) had neuropsychiatric illnesses of which 1 patient developed PRESS and she was hospitalized with death as outcome. She had class III lupus nephritis and took cyclophosphamide 4 days before the illness. Pulmonary manifestations were also seen in 35.9% (n=92) of patients.

Peptic ulcer disease (8.9%, n=23) and peritonitis (6.6%, n=17) were the common gastrointestinal manifestations. Dry eye (26.2%, n=67) and refractive errors (2.7%, n=7) were found to be the ophthalmic manifestations. About one third of patients, 100 (39.1%) had a vitamin D deficiency level of less than 20ng/ml. 7 patients (2.7%) had Rhupus (a combination of rheumatoid arthritis and SLE); 3 patients (1.2%) had osteoarthritis; and 12 patients (4.7%) had diabetes mellitus; and 5 (1.9%) had antiphospholipid antibody syndrome.

Overall, two thirds of the patients, 167 (65.7%) have 2 & more comorbidities. About 32 patients (12.4) had thyroid disease. All of the patients were started on antimalarial agent (chloroquine) and more than 95% of them put on adjunct systemic corticosteroid. Rhupus patients were also put on weekly methotrexate and folic acid. Details can be found on the following table located on the next page.

Table 5.4 Complications and comorbidities among SLE patients (n=256)

Variables	**Categories**	**Frequency**	**Percentages**
Cardiovascular disease	Hypertension	61	23.8%
	Heart disease	24	9.4%
	Stroke	15	5.9%
	Vasculitis	7	2.7%
Lupus nephritis	Yes	54	21.1%
Neuropsychiatric illness	Seizure disorder	13	5.1%
	Cognitive dysfunction	7	2.7%
	Depression	32	12.5%
Pulmonary disease	Pleurisy	19	7.4%
	Interstitial lung disease	12	4.7%
	Pulmonary TB	20	7.8%
	Pulmonary hypertension	41	16%
Gastrointestinal disease	Peptic ulcer disease	23	8.9%

	Peritonitis	17	6.6%
Ophthalmologic disease	Yes	74	28.9%
Vitamin D deficiency	Yes	100	39.1%
Rheumatoid arthritis	Yes	7	2.7%
Osteoarthritis	Yes	3	1.2%
Antiphospholipid antibody syndrome	Yes	5	1.9%
Diabetes mellitus	Yes	12	4.7%
HIV/AIDS	Yes	4	1.6%
Thyroid disease	Hypothyroidism Hyperthyroidism	27 5	10.5% 1.9%

Table 5.5 Logistic regression analysis of factors associated with SLE

Variables	Odds ratio (CI 95%)
Gender	
Female	2.83(1.29-6.22)
Male	3.5 (1.19-10.61)
Age	
18-34	2.11(1.01-4.22)
35-64	1.98(1.22-3.22)
≥65	3.85(1.76-8.55)
Hypertension	1.43(0.34-5.66)
Diabetes mellitus	2.15(0.61-7.32)
Heart failure	0.57(0.05-2.11)
Vitamin D deficiency	1.75(0.73-6.42)
Deranged lipid profiles	0.96(0.04-6.53)

OR=Odds Ratio, CI= confidence interval, P value<0.05

5.5. Laboratory features of the studied patients

Hematologic manifestations were present in 75.2% of patients and about one fourth of patients had anemia (n=68, 26.6%) and leukopenia (n=72, 28.1%). ANA was positive in 98.8% of the patients and an anti-dsDNA antibody was positive in 67.9% of patients. Both ANA and anti-dsDNA antibody tests were done in 181 (70.7%) of patients. More than three fourth of patients had elevated ESR & CRP (ESR>20 & CRP>15). 9 patients (3.5%) had low C3 and 13 (5.1%) patients had low C4 levels. Further information can be found in the following table.

Table 5.6 Laboratory features of the patients (n=256)

Categories	Variable	Frequency	Percentage
White blood cell count	Decreased	72	28.1%
	Elevated	4	1.6%

Hemoglobin	Decreased	68	26.6%
Platelet	Decreased	48	18.8%
Anti-nuclear antibody	Positive (titer>1:160)	253	98.8%
Anti-double stranded DNA antibody	Positive	174	67.9%
ACCP antibodies	Positive	7	2.7%
Lupus anticoagulant	Positive	5	1.9%
Acute phase reactants	Raised ESR Raised CRP	241 199	94.1% 77.7%
Complement level	Decreased	22	8.6%
Rheumatoid factor	Yes	86	33.6%
Serum Creatinine	Elevated	19	7.4%
Proteinuria	Yes	47	18.4%
Liver function test	Elevated	2	0.8%
Lipid profile	Deranged	88	34.3%
Coagulation profile	Deranged	5	1.9%

6. DISCUSSION

It has been discovered that African populations are more affected by the burden of SLE than previously thought. However, the impact of this disease in Ethiopia has not been evaluated before. Our study is the first to report on SLE in our region. This study is a 1 year retrospective chart review that aimed to assess the prevalence of SLE, clinical features, laboratory characteristics and comorbidities associated with SLE; of patients aged ≥ 18 years who visited adult rheumatology clinic of Tikur Anbessa Specialized Hospital. Overall, SLE appears to be a rare condition in the general population, but is more frequently observed among patients attending our rheumatology outpatient clinics.

Out of the total 3650 patients who visited adult rheumatology clinic of Tikur Anbessa Specialized Hospital in the year of 2022, 256 patients were diagnosed with SLE. The finding of this study showed that the prevalence of SLE is 7.01%. This result of the study is slightly higher than that of the prevalence of SLE in a rural tertiary center in South Nigeria[41] and Uganda[13], 4.7% & 5.5% respectively. It is also higher than the result of a systematic review and meta-analysis done among native sub-Saharan Africans showing the pooled prevalence of SLE among 28,575 participants was 1.7% (0.8–2.9%)[7]. This increasing prevalence of lupus might partially be attributed to improved diagnostic techniques in our country and increased awareness among healthcare professionals. As medical knowledge and technology advance, more cases might be identified and accurately diagnosed. On the other hand, the prevalence is lower than that of USA (23.2/100 000 person-years)[5]. This can be due to the socioeconomic disparities between developed and developing countries.

Our study showed that 94.1% of the patients were females with male to female ratio of 1:16 and the mean age of the patients was 34.2 years (SD±12.27). The duration of symptoms before the diagnosis was 6.5 months. This is similar with that of the study done in Kenya[10], Uganda[13] and globally[5]. Regarding risk factors, 63.7% had never smoked cigarettes and 9.8% of patients have family history of similar condition. A study done in Tunisia also showed that familial predisposition was present in 10.67% of the studied lupus patients which is comparable with our study[24]. Worldwide 35% of SLE patients have a history of smoking as in contrary to our study result[37]. Since most of our patients are females, smoking among females in our country is unusual and not widely seen. But they can be exposed to passive smoking and other

environmental smoke like indoor cooking. The occupational exposure and presence of prior infection were not documented in 53.9% & 63.7% of the cases respectively. This might be explained by physician's inability to ask detailed history or to document it on the patient's chart/electronic records due to high patient flow and work load at the rheumatology clinic.

In our study more than 75% of the patients presented with constitutional symptoms, dermatological manifestations and hematologic manifestations. This is identical to the finding of systematic review & meta-analysis of SLE among native sub-Saharan countries[7]. The results were Rheumatological (5.1%–99.9%), dermatological (4.3%–100%) and hematological (1.4–86.9%) manifestations were the commonest clinical features of SLE. Among the dermatological manifestations, chronic cutaneous lupus with discoid subtype was the most common in our setup (47.3%). This is similar to the study done in Uganda[13] and South Africa[21, 38]. Worldwide studies also showed that discoid cutaneous lupus is more common in black or African American races[5].

The common comorbidities seen in the studied SLE patients were cardiovascular diseases (41.8%) with hypertension being the most common 23.8%; followed by pulmonary comorbidities (35.9%); ophthalmic comorbidities in 28.9%; lupus nephritis in 21.1% and neuropsychiatric manifestations in 20.3% of the patients. Most of these findings are in line with that of Uganda[13] except that lupus patients in Uganda have higher prevalence of lupus nephritis, oral ulceration, dry eye as ophthalmic manifestation and neuropsychiatric comorbidity than our patients. This can be attributable to the fact that lupus nephritis patients in our set up might not come to the rheumatology clinic of our hospital as they could only have follow up at renal clinic, so they might not be registered in the logbook, making the prevalence of lupus nephritis lower than that of other African countries. Other variations of our study require further study for better explanation of the differences in comorbidities.

About 39.1% of the studied patients had a vitamin D deficiency level of less than 20ng/ml. A systematic meta-analysis in Africa concluded that inadequate levels of serum vitamin D are significantly high in patients with SLE compared to healthy subjects[17]. Our result also goes with the study done in Egypt[17] also showed that about high prevalence of vitamin D insufficiency and deficiency was detected as 73.3% and 23.3%, respectively.

ANA positivity in 98.8% of the patients and an anti-dsDNA antibody was positivity in 67.9% of patients show us that the accessibility and availabilities of these autoantibody tests is growing and improving in our country. But the affordability and lack of access to these tests in public and governmental hospitals remain a major challenge in our practice. Patients are often referred to private laboratories or outside the country for these tests.

The SLE-RA overlap was also seen in our study and 2.7% of patients had Rhupus. This is similar to worldwide studies as rhupus is a rare erosive arthritis[5, 7]. But it is lower than that of Uganda[13] in which the prevalence of rhupus being 20%. This might be due to failure to diagnose or neglect the possibility of rheumatoid arthritis in already diagnosed SLE patients as it is rare and clinicians are more focused on the SLE. In this setting therefore, it may be advisable to undertake serological investigation for both disorders to optimize management. Other autoimmune diseases like thyroid disease and diabetes mellitus were also observed just like other African and western countries.

All patients were initiated on standard dosages of antimalarial agent (chloroquine). Cyclophosphamide and azathioprine were initiated for lupus nephritis patients. Adjunctive treatment included the use of systemic corticosteroids, NSAIDs and vitamin supplementation. Patients with Rhupus were started on both chloroquine and a weekly methotrexate regimen with folic acid. These are identical management strategies with that of Uganda[13] and Nigeria[40].

Understanding the disease burden of systemic lupus erythematosus (SLE) can provide valuable insights into its socioeconomic impact and its effects on quality of life. This understanding is crucial for allocating resources effectively and improving the overall quality of life for individuals living with SLE. Additionally, it can offer clinicians and policy-makers important information to prioritize services and assess the impact of policy and practice decisions.

7. LIMITATIONS

Our study has some limitations due to its retrospective design. We were unable to evaluate the treatment outcomes, which is a major drawback. Additionally, the serological testing for ANA and dsDNA is not routinely performed in public healthcare services, and patients have to bear the cost of these tests privately. As a result, a few patients were unable to undergo these tests and were treated based on their clinical symptoms. However, this study is the first of its kind to describe the burden and characteristics of SLE in Ethiopia. Our findings will help healthcare professionals to improve clinical practice and guide future studies on the epidemiological trends, quality-of-life outcomes, treatment, and treatment outcomes of SLE patients in Ethiopia.

8. CONCLUSION

This study showed that the prevalence of SLE in our set up is 7.01% and more than one third of patients had extra-rheumatic manifestations and other comorbid illnesses. The prevalence of SLE in African countries, particularly in our country Ethiopia, is increasing from the previous one due to improving rheumatologic services with provision and increased availability of diagnostic studies. Majority of patients present to care with complications and cardiovascular diseases were the commonest comorbidities. Furthermore, other comorbid autoimmune illnesses like rheumatoid arthritis, thyroid disease and diabetes mellitus were not uncommon among SLE patients.

9. RECOMMENDATION

Most of our patients tend to seek medical attention when the disease has already reached advanced stages, which often leads to complications. It is crucial for primary care physicians and nurses to possess a greater awareness of the disease, as this would enable them to identify it early and initiate appropriate management promptly. This, in turn, has the potential to improve the overall prognosis for patients. We strongly recommend that clinicians maintain a high level of suspicion for patients who exhibit compatible clinical features of Systemic Lupus Erythematosus (SLE). Additionally, we propose the establishment of regional registers for SLE in various health bureaus and hospitals across different regions of the country. This would greatly assist in accurately assessing the local and regional burden of SLE in Ethiopia in order to guide and implement its management options in our set up. We also recommend that Ministry of Health Ethiopia should allocate budget for initiating various antibody tests used for diagnosis of SLE, located at least in the two large public hospitals with rheumatologic centers. This measure will ensure affordability and easy availability for the patient and physician.

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ANNEXES

Data collection sheet

ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH AND MEDICAL SCIENCES

DEPARTMENT OF FAMILY & COMMUNITY MEDICINE

Data Collecting Format on the prevalence and associated factors of SLE at adult rheumatology clinic of Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia for the past 1 year.

1. Date: _____/_____/_____

2. Card no: _____

3. Name of health facility: Tikur Anbessa Specialized Hospital

4. Name of data collector*:* _____

Part I: Socio demographic status of the patient	
Questions	Responses
1.Age in years	A. 18-34 B. 35-64 C. ≥65
2.Gender	A. Male B. Female
4. Residence	A. Urban B. Rural
5.Religion	A. Muslim B. Christian C. Other
6.Marital status	A. Married C. Widowed/widower B. Single D. Divorced
7.Occupational status	A. Salaried employee D. Housewife B. Merchant E. Student C. Farmer F. Other
9.Duration of symptoms before diagnosis in	_____

years	
Part II: Identified risk factors for SLE	
Family history of similar condition	A. Yes B. No C. Not documented
Occupational chemical exposure	A. Yes B. No C. Not documented
Prior infection	A. Yes B. No C. Not documented
Smoking history	A. Yes B. No C. Not documented
Part III: Clinical features/comorbidities/complications	
Constitutional symptoms	A.Fever B.Fatigue C.Myalgia D.Arthralgia _____
Cardiovascular disease	A. Hypertension B. Heart disease C. Stroke D. Vasculitis E. Other F. None
Pulmonary disease	A. Infection B. Interstitial lung disease C. Pleuritis D. Pulmonary hypertension E. Other F. None

Gastrointestinal disease	A. Peptic ulcer disease B. Dysphagia C. Peritonitis D. Other E. None
Lupus nephritis	A. Yes B. No
Diabetes mellitus	A. Yes _____ B. No
Ophthalmologic complication	A. Yes _____ B. No
Dermatologic illness	A. Acute cutaneous lupus B. Subacute cutaneous lupus C. Discoid lupus D. Other E. None
Neuro-psychiatric illness	A. Aseptic meningitis G. Anxiety disorder B. Seizure disorder H. Other C. Cognitive dysfunction I. None D. Peripheral neuropathy E. Depression F. Psychosis
Other comorbidities	A. Autoimmune diseases _____ B. Infections _____ C. Osteoarthritis D. None
Part IV: Laboratory features	

CBC profile	A. WBC B. HGB C. Platelet
ANA	A. Positive B. Negative C. Not done
Anti dsDNA antibodies	A. Positive B. Negative C. Not done
Other antibodies done	A. Positive _____ B. Negative C. Not done
Acute phase reactants	A. ESR B. CRP C. None
Serum vitamin D level	A. Done - _____ B. Not done
Liver function tests	A. Normal B. Elevated C. Not done
Renal function tests	A. Normal B. Elevated C. Not done
Proteinuria	A. Yes B. None
Lipid profiles	A. Normal B. Elevated C. Not done
Coagulation profiles	A. Normal B. Deranged C. Not done