PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS ATTENDING RHEUMATOLOGY CLINIC IN KENYATTA NATIONAL HOSPITAL

DISSERTATION WRITTEN IN PART OF FULFILMENT OF THE DEGREE OF MASTER OF MEDICINE IN INTERNAL MEDICINE, UNIVERSITY OF NAIROBI

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DECLARATION

This dissertation is my original work and has not been presented for a degree at any other university

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LIST OF ABBREVIATIONS

ACR	American college of Rheumatology
ANA	Antinuclear Antibody
Anti-dsDNA	Anti-double-stranded DNA
Anti-SM	Anti-Smith antibody
APS	Antiphospholipid Syndrome
CBC	Complete blood count
CNS	Central Nervous System
DNA	Deoxyribonucleic Acid
EQ 5D	EuroQoL-5D
GI	GastroIntestine
HRQOL	Health Related Quality of Life
HCQ	Hydroxychloroquine
IgG	Immunoglobulin
KNH	Kenyatta National Hospital
KNH/UON ERC	Kenyatta National hospital University of Nairobi Ethics Review Committee
LE cell	Lupus Erythematosus cell
LupusQoL	Lupus Quality of Life Questionnaire
MMF	Mycophenolate Mofetil
NSAIDs	Nonsteroidal anti-inflammatory drugs
NP	Neuropsychiatric
QOL	Quality Of Life
QOLS	Quality of Life Scale
RA	Rheumatoid Arthritis

SF-36	Medical Outcomes Study Short Form -36
SF-6D	Short Form-6D
SLE	Systemic Lupus Erythematosus
SLE QI	Systemic Lupus Erythematosus Quality Indicators
SLICC	Systemic Lupus International Collaborative Clinics
SCC	SLE Symptom Check List
WHOQOL bref	World Health Organisation Quality Of Life Questionnaire (brief)
WHOQOL-100	World Health Organisation Quality Of Life Questionnaire (full)

ABSTRACT

BACKGROUND

Systemic Lupus Erythematosus is a chronic autoimmune disease that affects all organs of the body. It is becoming increasingly clear that SLE is not as rare in Kenya as was previously thought. Due to its chronicity SLE has been known to affect the quality of life of those affected by it. There is minimal data on SLE in East Africa and especially in Kenya. The quality of life of SLE patients in this country has never been assessed.

OBJECTIVES

The main objective was to document the quality of life of patients with SLE in Kenyatta National Hospital using LUPUS QOL. The secondary objectives were to correlate health related quality of life with duration of illness, drugs used and age of the patient.

STUDY DESIGN

This was a cross section study

STUDY POPULATION

Patients attending Rheumatology clinic in Kenyatta National Hospital.

METHODS

Patients who satisfy the ACR criteria were consecutively recruited. Consent was obtained and their demographic data retrieved from their files. Patients were examined for the presence of malar rash, discoid rash, arthritis/athralgia, photosensitivity, CNS symptoms, serositis and oral ulcers. The patients then filled the LUPUS QOL questionnaire. The information acquired was then analysed using SPSS version 17.0. The quality of life was calculated and then correlated with age, duration of illness and drug management.

RESULTS

Sixty two patients were studied (60 females, 2 males) with a mean age of 37.3years (range 14-71 yrs). Mean age at diagnosis was 34.5 years with mean duration of illness was 1.5 years. Patients scored globally low in all domains of the LUPUS QOL questionnaire. Highest domain was Planning 63.7 (29.3), Emotional Health 61.3 (26.5), Burden to Others 58.9 (31.2), Fatigue57.5 (30.0), Pain 56.6 (29.6), Physical Health 54.0 (23.3), Body Image 47.1 (24.2) Intimate Relations 41.1 (38.4). HRQOL correlated positively with advance in age for the domains Physical health, Burden to others, Emotional health and Fatigue.There was no correlation between HRQOL and duration of illness or drugs used by the population.

CONCLUSION

Patients with SLE were found to have a poor quality of life. The health related quality of life was found to correlate with advance in age in the domains of Physical health, Burden to others, Emotional health and Fatigue. However there was no correlation between health related quality of life with duration of illness or the medications used by the patients.

1 . LITERATURE REVIEW

1.1. INTRODUCTION

Systemic lupus erythematosus is a chronic inflammatory autoimmune disease that affects all organs of the body. The organs undergo damage mediated by tissue binding auto antibodies and immune complexes.

1.2 HISTORY

Lupus is latin for wolf[1] (RG., 1987,1)[1] . History of lupus is divided into three periods. Classic period is during the 13th century when it was first described by the physician Rogerius. He described the erosive facial lesions as being wolf bites.

The period from 1872 is described as the neoclassical era when Karposis described the other manifestations which were subcutaneous nodules, arthritis, lymphadenopathy, fever, weight loss, anaemia and CNS involvement[2].

The modern era is characterized by the discovery of the Lupus Erythematosus (LE) cell, found in the bone marrow, by Hargraves in 1948. Familial occurrence of lupus was first noted in 1954.

1.3 EPIDEMIOLOGY OF SLE

Reports of SLE among African blacks were initially thought to be rare in comparison with African Americans, where the incidence is actually higher than Caucasians[3].

The frequency of SLE varies by race and ethnicity, with higher rates reported among black and Hispanic people. The prevalence of SLE is approximately 40 per 100,000 whites in Rochester, Minnesota, versus 100 per 100,000 Hispanic persons in Nogales, Arizona.[4,5]

Prevalence of SLE appears to vary by race. However, because of different prevalence rates among people of the same race in different geographical locations, a clear conclusion cannot yet be drawn. Low reported rates of SLE in Africa in contrast to a high prevalence in black women in the United Kingdom suggests the importance of environmental influences.[6] In addition, the influence of race on prognosis has been widely debated. The LUMINA study group examined

SLE among black, white, and Hispanic patients in the United States (including Puerto Rico) and reported that both disease activity and poverty predicted higher mortality among racial and ethnic minorities.[7]

A study done in London found that of the 100 patients, 96 were women and four men. Most of them were Caucasians, with the least being Africans and
Indians. Mean age at onset of the first symptom was 29.6 years[8]

A study done in Greece looking at the most prevalent demographic features in lupus patients showed that Several differences in the expression and morbidity of the disease were found in relation to the gender of the patient. Male patients had a higher prevalence of thrombosis, nephropathy, strokes, gastrointestinal tract symptoms and Antiphospholipid Syndrome when compared with female patients, but tended to present less often with arthralgia, hair loss, Raynaud's phenomenon and photosensitivity as the initial clinical manifestations. [9]

SLE has rarely been reported among African Blacks, in contrast with African-Americans. Such reports have been mostly case reports. First recorded case in Africa was in 1960 by Trowel[10] ..in 1961 only 8 cases were recorded in Uganda.[11] However it is becoming increasingly obvious that this disease may not be rare after all in africa.SLE was unknown in sub-Saharan Africa before 1960 but with improved healthcare and better laboratory facilities, more and more cases of SLE are being picked up in sub-Saharan Africa.[12]

In Zimbabwe a study by Taylor of 31 patients found average age at diagnosis to be 28 years. Peripheral deforming arthritis was the commonest clinical manifestation (81%) followed by renal disorder 71%, with skin disease being the least (16%)[13]

A study of 66 patients with SLE done in Nigeria reported that, females were 95.5% and males were 4.5% with a mean age of 33 years. The most common clinical presentation was polyarthritis (87%) followed by fever (50%), hair loss (45%) and discoid rashes (43%). [14]

In Northern Africa, a hundred patients with SLE, seen at the Department of Internal Medicine of the University Hospital La Rabta in Tunisia over a 15-year period (1987 to 2001) were studied. There were 92 women and eight men with an average age at the onset of disease of 32 years. Of

the patients, most common clinical features were articular involvement, photosensitivity and malar rash.[15]

Most of the studies on SLE in sub Saharan Africa have been done in South Africa. They clearly show that SLE is not as rare as previously thought among black Africans.[16,17]

Ward compared clinical manifestations of SLE in both black and white patients. Race was found to influence the clinical features of SLE. Blacks had more discoid lesions and proteinuria and less photosensitivity. They also had more psychosis and serositis. Black patients were also found to be younger, more females and had a lower SES.[16]

Malokhia demonstrated that SLE has a prevalence (per 100000) of women in an area of south London and estimated it to be 177 (95% CI 135-220) in Afro-Caribbeans, 110 (58-163) in west Africans, and 35 (26-43) in Europeans. The high prevalence of SLE in recent migrants from West Africa suggests that the disease is not rare in West Africa, and that there is a genetic basis for the high risk of SLE in people of West African descent compared with other group[17].

A study looking at the predictors of death in a population of SLE patients in S. Africa, in which the female to male ratio was 18: 1,found the mean age at presentation to be 34 yrs. Arthritis, nephritis and neuropsychiatric disease had a cumulative frequency of 70.4%, 43.8% and 15.9% of patients, respectively as the commonest presentations.[18]

Another study in S.A. done by Carey based in the University Hospital of Bloemfontein showed that of 76 patients visiting the university hospital clinic, 71were females. African patients accounted for 61.3% of the study population, whites for 33.9%, Asians for 1.6% and coloureds for 3.2%. Patients most frequently had immunological (90.8%), mucocutaneous (86.9%), musculoskeletal (85.5%) and cardiovascular problems (77.6%).[19]

Tikly did a study concentrating on the cluster of autoantibodies in patients with SLE. These were 111 black South Africans (103 females and 8 males). The mean age of the patients was 35.1 years. The commonest clinical and laboratory features noted were arthritis (62.2%), hypocomplementaemia (61.2%), haematological abnormalities (60.5%) and malar rash (55%). The serological abnormalities included antinuclear antibodies (98.2%), anti-dsDNA (66.2%),

anti-Sm (44.2%), anti-RNP (65.5%), anti-Ro (60.5%), anti-La (28.4%) and rheumatoid factor (10.1%).[20]

Data on SLE in Kenya is wanting. A study done in Kenya at the KNH, over a period of 7 years (1981-1988) a total of 67 patients were diagnosed with SLE. They however only assessed for lupus nephritis and it was found that a large number of them (23) had lupus nephritis.[11] Prior to this, a survey done in 1967 actually found only one report of lupus in Kenya. Other than this, there is not a lot of information on SLE in Kenya.

1.4 CLINICAL FEATURES

Although exact aetiology is unknown, many of the clinical features are mediated directly or indirectly by antibody formation and the creation of immune complexes. The clinical features of lupus can be divided into two broad categories; the constitutional symptoms and symptoms according to the specific organ involved.[21]

The constitutional symptoms are mainly fatigue, weight changes and fever.

1.4.1 Fatigue

Fatigue is the most common and debilitating feature. It occurs in more than 80% of the patients and its presence does not necessarily correlate with disease severity, though some studies have found that most patients with fatigue had active disease[22].

1.4.2 Fever

In a cohort study involving seven European countries, Cevera found fever to be present in 16.3% of the patients (n=1000). Fever may be caused by lupus itself. It may also be caused by infections or the drugs used by the patient[23].

In his series, Stahl found that 60% of his patients had fever due to lupus alone, and only 23% had fever due to infection[24].

1.4.3 Weight changes

Weight changes are frequent and can be related to lupus or the drugs. Weight gain can be due to hypoalbuminaemia and/or renal disease causing fluid retention or the medication used by the patient.Weight loss can be due to reduced appetite, diuretics, gastrointestinal side effects of drugs.

SPECIFIC ORGAN SYMPTOMS

1.4.4 Haematological

The major haematologic manifestations of SLE are anaemia, leucopaenia, thrombocytopaenia, and the Antiphospholipid Syndrome (APS). Anaemia is most common and is multi-factorial. Anaemia is usually anemia of chronic illness but can also be iron deficiency anemia or hemolytic anaemia. [25]

1.4.5 Renal

Renal disease is clinically apparent in almost half of the patients. An abnormal urinalysis with or without an elevated plasma creatinine concentration is present in a large proportion of patients at the time of diagnosis, and may eventually develop in up to 75 percent of cases. The most frequently observed abnormality is proteinuria.[26]

1.4.6 Musculoskeletal

Joint symptoms occur in more than 90% of the patients and are the most common early presentations of lupus. Arthritis and athralgia are seen in more than 95% of the patients and they are usually migratory. Synovial involvement was rare and effusion is usually small.[2] Osteoporosis[27] and myalgia are also common. Myalgia is also seen in patients with active disease[28],

1.4.7 Mucocutaneous

Most common is the malar rash, discoid lesions and alopecia. More than 70% of patients in a series had at some point skin manifestations. Of these 40% had malar rash, while 24% had alopecia and 19% had oral ulcers.[29]

1.4.8 Gastrointestinal

The gastrointestinal (GI) system is often more involved due to side effects of drugs especially NSAIDS and glucoccorticoids and occurs in upto 40% of patients. Sultan reviewed lupus patients and found that the most common GI manifestations of SLE include mouth ulcers, dysphagia, anorexia, nausea, vomiting, haemorrhage and abdominal pain.[30]

1.4.9 Pulmonary

Pulmonary disease is found more in lupus than in any other connective tissue disease. Lupus can affect the lung, its vasculature, the pleura, and/or the diaphragm. In some cases, the only detectable abnormality may be abnormal pulmonary function tests. Primary intrathoracic manifestations include pleural disease (effusions and/or thickening), acute lupus pneumonitis, sub acute interstitial lung disease including bronchiolitis obliterans organizing pneumonia and non-specific interstitial pneumonia with fibrosis, chronic interstitial lung disease of interstitial pneumonia, pulmonary hemorrhage, pulmonary vascular disease, small airway disease of bronchiolitis obliterans, and pulmonary arterial hypertension.[31]

1.4.10 Cardiovascular

Cardiac disease is common among patients with systemic lupus. Pericardial, myocardial, valvular, and coronary artery involvement may occur. Pericardial disease is the most common [32] Mitral valve disease is the most common[33].

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1.4.11 Central Nervous System

Neurologic complications include cognitive defects, organic brain syndromes, delirium, psychosis, seizures, headache, and/or peripheral neuropathies. Other less common problems are movement disorders, cranial neuropathies, myelitis, and meningitis.

There are over 19 neuropsychiatric disorders associated with lupus as per ACR definitions.[34] Using these definitions, the most to the least common are cognitive dysfunction, headache, mood disorder, cerebrovascular disease, seizures, polyneuropathy, anxiety, and psychosis.

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2. DIAGNOSTIC FEATURES OF SLE

The diagnosis is lupus is based on both the clinical features and the laboratory findings. The diagnosis of SLE is satisfied when 4 of 11 of these criteria are present. The criteria are > 90% sensitive and specific but are associated with several weaknesses.[35]For example, many patients with biopsy-proven lupus nephritis do not meet the criteria. Further, numerous advances in imaging, serologic and cerebrospinal fluid testing have rendered the central nervous system (CNS) definition outdated. The Systemic Lupus International Collaborative Clinics (SLICC) has proposed new criteria for the disease, which are in the process of being validated.[36]

However, for now the revised criteria of the American College of Rheumatology (ACR) is used for the diagnosis of SLE.

TABLE 1: DIAGNOSTIC CRITERIA FOR LUPUS[36]

Cutaneous	1. Malar rash: fixed malar erythema, flat or raised
	2. Discoid rash: erythematous raised patches with keratic scaling and follicular plugging; atrophic scarring may occur
	3. Photosensitivity: skin rash as an unusual reaction to sunlight; diagnosed by patient history or physician observation
	4. Oral ulcers: oral or nasopharyngeal ulcers, usually painless; observed by physician
Systemic	1. Arthritis: nonerosive, involving ≥ 2 peripheral joints; characterized by tenderness, swelling, effusion
	2. Serositis: pleuritis (convincing history of pleuritic pain or rub heard by physician, or evidence of pleural effusion) or pericarditis (documented by electrocardiogram, rub, or evidence of pericardial effusion)
	3. Renal disorder: persistent proteinuria (> 0.5 g/d or > 3+) or cellular casts of any type
	4. Neurologic disorder: seizures or psychosis in the absence of other causes
Laboratory	1. Hematologic disorder: hemolytic anemia or leukopenia (< 4000/mm^3 on 2 occasions), lymphopenia (< 1500/mm^3 on 2 occasions), or thrombocytopenia (< 100,000/µL in the absence of offending drugs)
	2. Immunologic disorder: anti-dsDNA or anti-SM, or antiphospholipid antibodies (abnormal IgM or IgG anticardiolipin antibody, lupus anticoagulant, or false-positive syphilis serology)
	3. ANA in the absence of drugs known to be associated with the "drug-induced lupus syndrome"

= American College of Rheumatology; ANA = antinuclear antibody; anti-dsDNA = anti-double-stranded DNA; anti-SM = anti-Smith antibody; IgG = immunoglobul

If 4 of these criteria, well documented, are present at any time in a patient's history, the diagnosis

is likely to be SLE. Specificity is 95%; sensitivity is 75%.

Lupus can be classified as organ threatening or non organ threatening. Organ-threatening disease includes renal disease, CNS vasculitis, cardiopulmonary disease, hepatic and hematological abnormalities and is present in approximately 50% of patients with SLE. Organ-threatening disease is associated with high morbidity and mortality that is most commonly related to complications such as thrombosis, cardiopulmonary disease, renal disease, and infection.

Non organ-threatening SLE is typically characterized by constitutional, cutaneous, and musculoskeletal manifestations. The most common signs/symptoms include malaise/fatigue, arthralgia/myalgia, skin rash, fever, and butterfly rash. Although not life threatening, these manifestations cause pain, discomfort, debilitation, altered perception of body image, and decreased quality of life.

3. TREATMENT OF SLE

In the treatment of SLE , there are different drugs that can be used. They are classified in Table 2. Because the disease is chronic and incurable, the treatment is aimed at suppressing disease activity, which is reversible, and at preventing the appearance of organ injuries caused by the disease, and of side effects secondary to the drugs used, in addition to controlling associated comorbidities[35].

Periodic follow-up and laboratory testing, including urinalysis, complete blood count (CBC) with differential, and creatinine, are imperative to detect signs and symptoms of new organ-system involvement and to monitor the response or adverse reactions to therapies. At least quarterly visits are recommended in most cases[37]

TABLE 2: DRUGS USED IN TREATMENT OF LUPUS

Drug Class	Comments
NSAIDs	Used for fever, headache, serositis, arthralgia/arthritis, myalgia
Antimalarial agents	Hydroxychloroquine ; disease-modifying and steroid-sparing properties
	Quinacrine or chloroquine can be used for resistant skin lesions
Corticosteroids	approved for SLE
	Dose:– Organ-threatening: 1 mg/kg per day for 4-6 weeks, followed by tapering– Nonorgan-threatening: ≤ 0.25 mg/kg
Immunosuppressant agents	Methotrexate: indicated for synovitis, and some constitutional and cutaneous manifestations
	Azathioprine: effective for synovitis; steroid-sparing in patients with organ-threatening d sease
	Cyclophosphamide: effective for nephritis and CNS vasculitis; useful in selected patients with organ-threatening disease
	Mycophenolate mofetil: effective for nephritis; unproven for other disease manifestations
	Leflunomide: effective for synovitis and some constitutional and cutaneous manifestations
	Cyclosporine: may be useful for membranous nephritis, bone marrow hypoplasia or aplasia, certain refractory rashes

CNS = central nervous system; NSAIDs = nonsteroidal anti-inflammatory drugs; SLE = systemic lupus

The ACR has recommended follow up and assesment tests based on the drugs as shown in the table above. The treatment recommendations depend on disease manifestations.[38] Fever, cutaneous manifestations, musculoskeletal manifestations, and serositis represent milder disease, that are normally controlled with low-potency medications or short steroid courses.

CNS involvement and diffuse proliferative renal disease are recognized to be severe manifestations and are treated with more aggressive immunosuppression.

4. QUALITY OF LIFE

4.1 ASSESSMENT OF SLE

A group of rheumatologists (Jinoos Yazdany et al) developed a set of quality indicators that are used to asses quality of healthcare of the individual with SLE. Long term survival of SLE patients has improved over the years due to improved care. However this has also led to increased incidences of long term complications from the disease itself and also from side effects of the medical therapies.

The SLE QI Advisory Panel Meeting came up with a quality indicator set. The 20 QIs cover several important aspects of SLE care including diagnosis, general preventive strategies (e.g. vaccinations, sun avoidance counseling), osteoporosis prevention and treatment, screening for cardiovascular disease, drug toxicity monitoring, renal disease, and reproductive health. The QIs provide an initial tool for assessing health care quality in SLE.[39]

During the clinical follow-up of a patient with SLE, the physician should answer the following questions: has the disease improved, worsened, or remained stable?; is the presence of irreversible injury due to the disease or to the treatment instituted?; what is the patient's perception about his/her health status and quality of life, since it often differs from that of the physician?[35]

Systemic lupus erythematosus is characterized by periods of active disease and remission. With better healthcare, The survival of SLE patients has significantly improved over the past years [40,41]

It is now becoming clear that disease status in chronic conditions is not only measured by the physical condition of the patient but also psychosocial factors such as pain, apprehension, difficulty in fulfilling personal and family responsibilities, financial burden and diminished

cognition. [42] Assessing the quality of life (QOL) is thus an important measure to assess how much the disease process and its treatment is affecting an individual.

According to WHO,quality of life is defined as the individual's perception about his/her physical, mental, and social well being, and not merely the absence of disease or infirmity.[43]It comprises of several domains i.e.physical health, psychological status, degree of independence, social relationship, beliefs, relationship with the environment, financial gain, and freedom. Measures of QOL consider the effects of the disease or its treatment from the patient's perspective and determine the need for social, emotional and physical support during illness.

Khana did a study using WHOQOL-bref questionnaire and found that higher disease severity was associated with a lower quality of life score especially in the physical and psychological aspects but no significant correlation with social and environmental domains in the QOL. Patients with clearly active and probably active disease had significantly lower scores in the physical and psychological domains than patients with inactive disease. However, no significant difference was found in the domains of social and environmental QOL. Age or disease duration did not affect the QOL in any of the domains [44].

Rinaldi in Italy found that Both physical and mental component summary scores of the SF-36 were reduced in patients with SLE compared with controls of healthy people. The Physical component score and the mental component scores were higher more frequently in controls than in lupus patients (81 *vs* 48.4%, $P<0.00001$). They also found that HRQOL tended to worsen with age. [45]

Factors that have been shown to affect quality of life are both physical and psychological. Some of the psychological factors are stress learned helplessness and social support[46,]. Stress, vulnerability to stress and anxiety have been demonstrated to affect the quality of life of lupus patients. This is because patients with lupus have been found to have fewer and less effective coping strategies than the general population. This fact was further amplified by the fact that teaching patients coping mechanisms markedly improved their quality of life[47].

Tam also demonstrated that anxiety and depression affected negatively the quality of life , with depressed patients having a poorer quality of life. And this was found to impact negatively on their quality of life scores[48].

The Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) is a generic instrument for QoL assessment. It is a multidimensional questionnaire formed by 35 items, grouped into the following eight domains: physical functioning; role limitations due to physical health; pain; general health perception; vitality; social functioning; role limitations due to emotional problems; and mental health. It includes one more question about the current health perception as compared with that of one year before, which is not included in the score calculation. The final score ranges from zero to 100, in which zero corresponds to the worst general health perception and 100 to the best general health perception[49].

In a meta-analysis, Castellino looked at the different questionnaires for the measurement of QOL. He looked at a total of 13 papers. Six were validation studies for generic instruments and used the Short Form-36 (SF-36) (n=4), Quality of Life Scale (QOLS), EuroQoL-5D (EQ-5D) or the Short Form-6D (SF-6D). The remaining seven papers employed one of the disease-specific measures: SLEQOL, L-QOL, SLE Symptom Check List (SSC), LupusQoL (UK) and LupusQoL (US). SF-36 and all the disease-specific measures had good internal consistency. All the measures demonstrated good construct validity, test-retest reliability and interpretability. All the disease-specific measures had acceptable administration time, comprehensibility and content validity.[50]

Using the LUPUS QOL , the quality of life in a predominantly African American (60% of the population) was evaluated. The findings demonstrated that fatigue and physical health were the most affected domains and intimate relationship was the least affected domain. Increase in age adversely affected physical health ,pain and body image . They also found that married patients had less pain and better physical health[51].

Using the same LUPUSQOL questionnaire, a study in Mexico found that the population, consisting of mainly women scored poorly in all the domains. The burden to others domain had the least score and th domain with the highest score were planning and body image[52].

LUPUSQOL questionnaire was also validated for use in the French population and the patients here were generally found to score better. The patients had minimal disease activity as per their SLEDAI score and this was suggested to contribute to their lower scores[53].

4.2 LUPUS QUALITY OF LIFE (LUPUSQOL)

LUPUSQOL is a quality of life questionnaire. It was developed to measure disease specific health-related quality of life (HRQOL) in adults with systemic lupus erythematosus (SLE). It was developed and validated in the UK by McElhone et al in 2007 [54].

4.2.1 Individual subscales

1) Physical health (8 items),
2) Emotional health (6items),
3) Body image (5 items),
4) Pain (3 items),
5) Planning (3items),
6) Fatigue (4 items),
7) Intimate relationships (2 items),
8) Burden to others (3 items).

The Questionnaire has a 5-point Likert scale response format (0 all the time, 1 most of the time, 2 a good bit of the time, 3 occasionally, and 4 never). It has a recall period of the prior 4 weeks. It is available in both written and electronic versions.

4.2.2 Scoring

Scores range from 0 (worst HRQOL) to 100 (best HRQOL) and the mean raw domain score is divided by 4 and then multiplied by 100. The result represents the transformed score for that domain. Transformed domain scores are obtainable when at least 50% of the items are answered. The mean raw domain score is then calculated by totaling the item response scores of the answered items and dividing by the number of answered items. A non applicable response is treated as unanswered and the domain score is calculated. It takes roughly 20 minutes for the respondent to complete the questionnaire

4.2.3 Score interpretation.

The score ranges from 0 (worst HRQOL) to 100 (best HRQOL).

4.2.4 Validity.

Concurrent validity was assessed by comparing domain scores of the LupusQoL with SF-36 and it was found to have good correlation (r 0.71-0.79) when compared with other comparable domains of (SF-36). Recent studies done in the UK, US and Spain found that the LupusQoL has discriminant validity in that it functions relatively independently as an outcome measure in SLE. [61] This study found weak or no associations with factors such as disease duration, disease activity and damage . Patients with more active disease generally reported poorer HRQOL across all domains except fatigue.

5.1 STUDY JUSTIFICATION

SLE is a disease that has been studied extensively in other countries especially the Americas and European community. The information we use to manage our patients here is based on these studies.

This study will give baseline information on SLE in our country and form the basis for other studies.

In Africa, most of our SLE data is from Southern Africa. It is however becoming increasingly clear that the cases are increasing in number even in our country Kenya. With improved medical care and better diagnostic facilities available in the country in this day and age, more and more patients are being diagnosed with SLE.

These patients are also surviving longer. Thus the quality of life of these patients is important. The study will also act as a clinical audit on our management of SLE patients since it will look at matters from the patient's perspective.

However, we do not have studies based on our population and so we do not know if the disease pattern, morbidity and mortality trends in this country are the same as in the international community.

The study may also form a basis for developing policies on SLE that are tailored towards the Kenyan patient.

5.2 RESEARCH QUESTION

What is the health related quality of life of SLE patients attending Rheumatology Clinic?

5.3 BROAD OBJECTIVE

Determine health-related quality of life in patients with systemic lupus erythematosus

5.4 SPECIFIC PRIMARY OBJECTIVE

a) Determine the health related quality of life using the Lupus QOL questionnaire

SECONDARY OBJECTIVE

a) Document the current drug management

b) Correlate quality of life with age, duration of illness and medication used

5.6 STUDY DESIGN

This was a cross sectional study.

5.7 STUDY SITE

The study was carried out at KNH at the Rheumatology clinic.

5.8 STUDY POPULATION

The patients included were those who have satisfied the American College of Rheumatology (ACR) criteria[45] for SLE and are on follow up at the Rheumatology clinic.

5.8.1 Inclusion criteria

a) Patients diagnosed with SLE as by the ACR criteria and confirmed by a rheumatologist

b) Patients who gave Informed consent

c) For minors informed assent was obtained from their guardians

5.8.2 Exclusion criteria

a) Those who declined to participate in the study

5.9 STUDY VARIABLES

Demographic data

- Age,
- Gender,
- Age at diagnosis/duration of illness
- Marital status
- Level of education
- Clinical features -malar rash; discoid rash; photosensitive rash;

oral ulcers; Athritis/athralgia

Drugs – prednisone; methylprednisone; methotrexate; calcium channel blockers; NSAIDS; immunomodulators

5.10 SAMPLE SIZE

All patients with SLE attending the Rheumatology clinic were included in the study.

5.11 SCREENING AND RECRUITMENT

Patients were recruited using convenience sampling method. The patients eligible for the study were screened using information acquired from their files. These patients were included in the study after counseling and giving informed consent.

5.13 METHODS

All SLE patients attending the clinic were documented. The patients were screened using information in their files and those who fulfilled the ACR criteria were called up. Those who agreed to take part in the study were recruited into the study after giving informed written consent and assent for the patients under 18. After getting informed consent or assent from the participants, the patient's demographic data and last prescription was obtained from the file. The patients were then taken through some counseling. This involved finding out what they knew about their disease and clearing any misconceptions they may have had concerning their illness and treatment.

Patients clinical history was taken and a physical exam was then done. The presence of malar rash, discoid rash, arthritis/athralgia, serositis and photosensitivity were noted. These were defined as per the ACR criteria (TABLE 1). After this the patient was given the LUPUS QOL questionnaire to fill.

6. DATA MANAGEMENT AND STATISTICAL ANALYSIS

Data was collected using structured questionnaires and was cleaned for errors and conflicting answers, missing entries and duplicate entries. The cleaned data was then exported to SPSS version 17.0 for analysis. Demographic variables (age) was summarized into means/ medians while gender, marital status were presented using percentages.

6.1 HEALTH-RELATED QUALITY OF LIFE

LUPUS QOL data was scored and analyzed using a standard scoring system resulting in scores between 0 and 100. The mean score with standard deviation was then calculated to determine the health-related quality of life (HRQOL) of the study population in each domain.

6.2 CORRELATION ANALYSIS

HRQOL mean scores were compared between patients on specific drugs (NSAIDS, anti-malarial agents, corticosteroids and immunosuppressant agents) and those not on such drugs using Student's t test. HRQoL was correlated with age, duration of illness, drugs using linear regression analysis. Statistical tests were performed at 5% level of significance (95% confidence interval).

7. ETHICAL CONSIDERATIONS

Permission to carry out the study was sought from the Kenyatta National Hospital / University Of Nairobi Research and Ethics Committee. Patients were enrolled after thorough counseling and subsequent informed consent duly signed. For those below eighteen but above thirteen, we ascertained that assent was sought from the patient and the guardian. Patient confidentiality was maintained at all times. There was no discrimination of any patients who declined enrollment. Patient usual care was not interrupted and if need be, facilitated by the principal investigator. Results were communicated to primary health care providers (results attached to file) and to the patients where possible without prejudice.

Data was entered into a password protected data base under the custody of the principal investigator.

8. RESULTS

8.1 DEMOGRAPHIC CHARACTERISTICS

Seventy one patients were screened according to patients' records. Our did not fill the ACR criteria. The patients were then contacted by telephone and asked to participate in the study. Three had passed away, 2 declined to participate. Therefore 62 patients were analysed. Of these, 60 were female (96.8%) and only 2 were male (3.2%). The mean age of the population was 37.3 years (range 14-71). All the patients had some level of education with 61.3% of the population having some form of tertiary education i.e degree, diploma or certificate. Most of the patients, 34 (54.8%) were married. The mean age of diagnosis was 34.5 years. And mean time from diagnosis of illness was 1.5 years. Table 3 shows the basic characteristics of the population.

TABLE 3: SOCIODEMOGRAPHIC CHARACTERISTICS OF LUPUS PATIENTS

Variable	**Frequency (%)**
Age, mean (SD)	37.3 (12.2)
Min-Max	14-71
Gender	
Female	60 (96.8)
Male	2 (3.2)
Level of education	
Primary	8 (12.9)
Secondary	16 (25.8)
Tertiary	38 (61.3)
marital status	
Single	26 (41.9)
Married	34 (54.8)
Divorced	1 (1.6)
Missing	1 (1.6)
Age at diagnosis, mean (SD)	34.5 (12.2)
Time from diagnosis in years, median (IQR)	1.5 (0.08-12)(0.8-3.0)

8.2 DISTRIBUTION OF COMMON LUPUS CLINICAL FEATURES IN OUR POPULATION

Majority of the patients ,88.7% had arthritis or athralgia. This was followed by oral ulcers at 32.3%, malar rash 59.7%, photosensitivity 58.1%, serositis 32.2%, CNS 27.4% The least common clinical feature was discoid rash 17.7%. Figure 1 shows the distribution of the clinical features in the population.

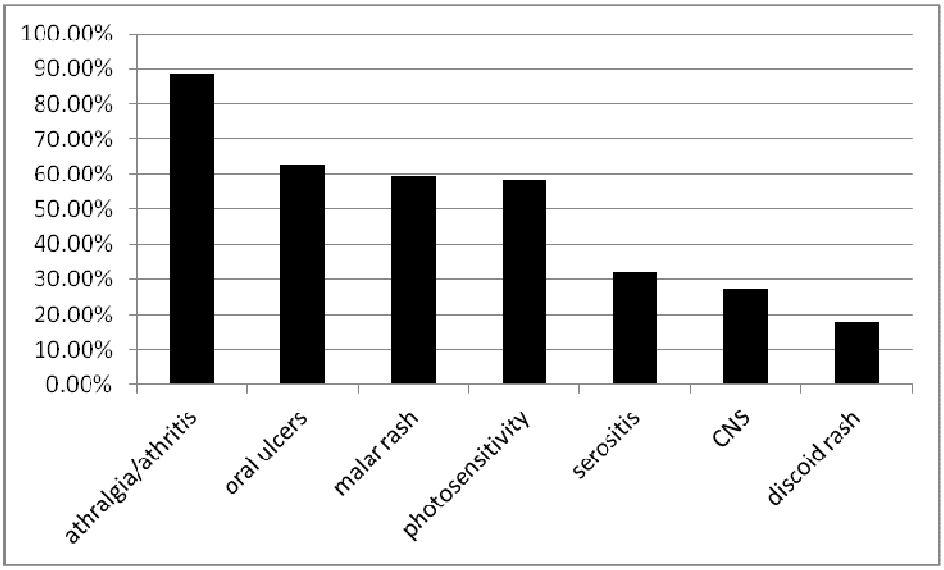

FIGURE 1. DISTRIBUTION OF COMMON CLINICAL FEATURES OF LUPUS IN THE POPULATION

8.3 HEALTH RELATED QUALITY OF LIFE

Our broad objective was to determine the HRQOL using the LUPUS QOL questionnaire. Our population scored globally low in all the domains. The domain with the highest scores was planning (63.7), followed by burden to others ,(58.9), fatigue (57.5), pain (56.6), physical health (54.0), body image (47.1) and the lowest intimate relationships (41.1). Table 4 summarizes the findings.

TABLE 4: LUPUS QOL SCORES OF OUR POPULATION

Domain	**Mean (SD)**
Physical health	54.0 (23.3)
Pain	56.6 (29.6)
Planning	63.7 (29.3)
Intimate Relations	41.1 (38.4)
Burden to others	58.9 (31.2)
Emotional heath	61.3 (26.5)
Body image	47.1 (24.2)
Fatigue	57.5 (30.0)

8.4 CURRENT DRUG MANAGEMENT IN OUR POPULATION

We recorded the patients' last prescription to get the current medication for each patient. Most common drug in use by our population was prednisone at 46(74.2%). This was followed by hydroxychloroquine (HCQ) at 43(69.4%). NSAIDS were the third most prescribed drug with 34 patients (54.8). Twenty three patients were on Azathioprine (37.1%). Methotrexate (MTX) was used by 14 (22.6%). The other drugs used by the patients were; Mycofenolate Mofetil (MMF) 5(8.1%) CCB 7 (11.3%), cyclosporine 2(3.2). Of note is that the 7 who were using CCB were all using it at antihypertensive doses. No one was using it for Reynaud's phenomenon. Figure 2 shows this distribution.

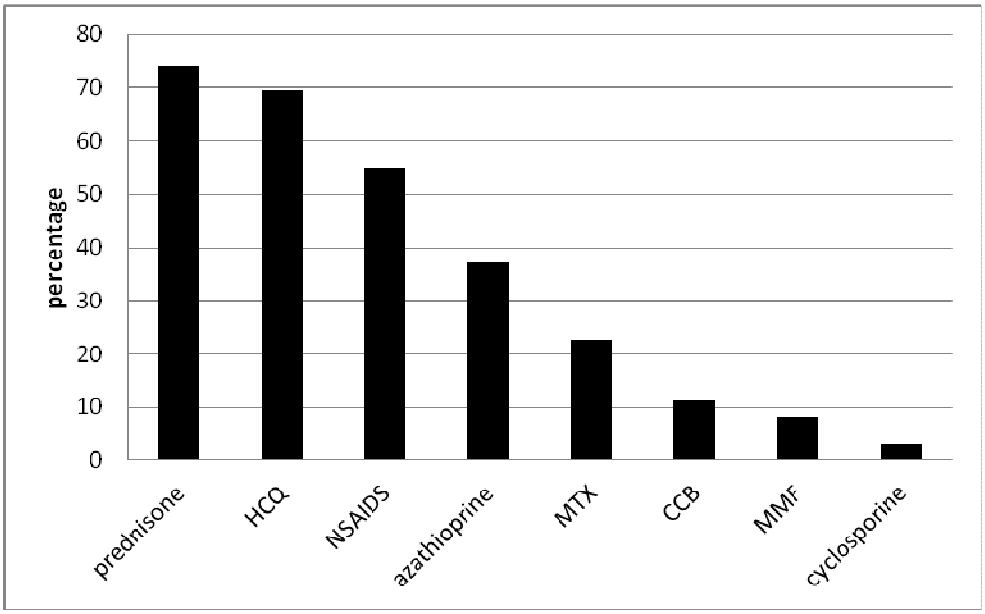

FIGURE 2. MEDICATIONS USED IN THE POPULATION

8.5 CORRELATION OF HRQOL WITH AGE

Quality of life scores of the population was correlated with age for each domain. Positive correlation was found between Physical health (r 0.306 p value 0.016), burden to others (r=0.272 p= 0.032) and emotional health (r=0.315, p= 0.013) and advance in age. Table 5 shows this correlation

TABLE 5: CORRELATION OF HRQOL SCORE AND AGE IN OUR POPULATION

Variable	**Pearson coefficient (r)**	**β (95% CI of β)**	**P value**
Physical health	0.306	0.58 (0.11-1.05)	**0.016**
Pain	0.128	0.31 (-0.31-0.93)	0.321
Planning	0.197	0.47 (-0.14-1.08)	0.125
Int. Relation	0.025	0.08 (-0.74-0.90)	0.848
Burden to others	0.272	0.72 (0.06-1.39)	**0.032**
Emotional heath	0.315	0.682 (0.15-1.21)	**0.013**
Body image	0.147	0.29 (-0.22-0.80)	0.258
Fatigue	0.268	0.58 (0.03-1.14)	0.039

8.6 CORRELATION OF HRQOL SCORE AND TIME FROM DIAGNOSIS OF ILLNESS

Table 6 shows the correlation between HRQOL and time from diagnosis of illness. There was no statistical significance between the two in any of the domains.

TABLE 6: CORRELATION OF HRQOL SCORE AND DURATION OF ILLNESS

Variable	**Pearson coefficient (r)**	**β (95% CI of β)**	**P value**
Physical health	0.191	2.04 (-0.69-4.77)	0.140
Pain	0.035	0.47 (-3.04-3.98)	0.791
Planning	0.067	0.89 (-2.57-4.35)	0.609
Int. Relation	0.135	2.38 (-2.22-6.97)	0.305
Burden to others	0.129	1.91 (-1.92-5.74)	0.322
Emotional heath	0.049	0.60 (-2.56-3.76)	0.707
Body image	0.160	1.77 (-1.09-4.63)	0.221
Fatigue	0.072	0.88 (0.55-0.59)	0.587

8.7 ASSOCIATION BETWEEN QOL AND DRUGS USED

We also found no association between HRQOL and medication used in our population. We looked at the three most common drugs used i.e. prednisone, HCQ and NSAIDS. Again we found no significant correlation with the drugs used as shown in Table 7, Table 8, Table 9

TABLE 7: ASSOCIATION BETWEEN HRQOL AND PATIENTS USING PREDNISONE

	Prednisone		P value
	Yes (n=46)	No (n=16)	
Physical health	53.1 (23.1)	56.6 (24.5)	0.609
Pain	55.1 (29.5)	60.9 (30.4)	0.501
Planning	61.4 (28.6)	70.3 (31.5)	0.300
Int. Relation	39.8 (37.9)	44.8 (40.9)	0.660
Burden to others	59.1 (33.4)	58.2 (30.9)	0.926
Emotional heath	60.9 (27.6)	62.4 (24.0)	0.849
Body image	46.3 (24.7)	49.2 (23.6)	0.686
Fatigue	58.4 (26.6)	55.1 (28.8)	0.682

TABLE 8: ASSOCIATION BETWEEN HRQOL AND PATIENTS USING NSAIDS

	NSAIDS		P value
	Yes (n=34)	No (n=28)	
Physical health	51.6 (23.7)	57.0 (22.9)	0.364
Pain	51.2 (29.2)	63.1 (29.3)	0.115
Planning	58.6 (30.6)	69.9 (27.0)	0.130
Int. Relation	39.1 (36.2)	43.5 (41.4)	0.666
Burden to others	58.5 (34.6)	59.3 (30.5)	0.926
Emotional heath	63.8 (27.6)	58.3 (25.3)	0.422
Body image	47.3 (22.6)	46.8 (26.5)	0.939
Fatigue	58.3 (25.9)	56.5 (28.7)	0.803

TABLE 9. ASSOCIATION BETWEEN HRQOL AND PATIENTS USING HCQ

	HCQ		
	Yes (n=43)	No (n=19)	
Physical health	52.8 (23.7)	56.9 (22.9)	0.526
Pain	54.9 (28.6)	60.5 (32.1)	0.493
Planning	58.3 (30.3)	75.9 (23.6)	0.029
Int. Relation	39.3 (39.4)	45.2 (36.9)	0.583
Burden to others	58.0 (35.5)	60.8 (25.3)	0.761
Emotional heath	58.1 (26.6)	68.5 (25.5)	0.154
Body image	44.3 (24.7)	53.8 (22.4)	0.164
Fatigue	55.8 (27.3)	61.5 (26.5)	0.459

The rest of the drugs were being used by too few people to make any correlations. It was also not possible to make correlation between HRQOL and gender as there were only two men.

9. DISCUSSION

The mean age of the lupus patients was 37.3 years with the youngest being 14 and oldest 71. This could be because diagnosis of lupus takes time in our setting . This could either be due to reduced awareness of the disease or due to limited laboratory tests needed to make the diagnosis in many facilities in the country. However, even with the most experienced, the diagnosis may still be difficult due to the non specificity of the symptoms. Most of our patients reported they had symptoms for upto 3 years before the diagnosis of lupus was finally made. The Rheumatology clinic has also been running for a short period of time and this may also explain the short duration of illness in the population since a majority of the patients were diagnosed with Lupus at the clinic.

Lupus is mostly a disease of females of child bearing age and so it is not surprising that the population had only 2 males as opposed to 60 female (M:F 1:30). The male female ratio was also higher than in other studies, e.g , Wadee in S. Africa[18] found a male female ratio of 1:18. The smaller population may account for the higher male to female . In Nigeria, they found 95.5% of their patients were women. This is similar to this population which had 96.8% women and the S Africa population that found 94.7% of their population to be women[19].

In this population all the patients had some level of education with most of them (61.3%) having tertiary education. This could be because most of the population was derived from the urban centre and its environs. Most of the population, 54.8% was married.

Duration from diagnosis was 1.5 years, much lower than in other populations. The British had a duration from diagnosis of 9.2 years[54] while the Americans had a duration from diagnosis of 9.2 years[50]. In Nigeria the duration was 2.6 years.[14] Duration from diagnosis ranged from 1 month to 12 years. However when interviewing the patients, it was obvious that some patients had symptoms for up to three years before a diagnosis of lupus was made. This may explain the much shorter duration of illness.

The most common clinical feature was arthritis/athralgia (88.7%), followed by oral ulcers (32.3%), malar rash (59.7%), serositis (32.3%), CNS symptoms and discoid rash. At the time of being included in the study, most of the patients still had early disease duration ranging from 1 month to 12years which is when these symptoms are most commonly seen.

Studies done in Greece [9] and Zimbabwe [13] also found the most common clinical feature in the females in their population to be arthritis/ athralgia. This was also replicated in Tunisia (78%)[15] and in Nigeria by Adelowo (87%)[14]

The patients were found to have a poor HRQoL using LUPUS QoL. They scored poorly in all the domains of LUPUS QoL questionnaire. The domain with the highest score was Planning 63.7(SD 29.3). Planning domain involved asking patients if the disease had affected their ability to attend events, organize their lives or commit themselves to social arrangement. The possible reasons why the scores were so poor could be because the fatigue experienced by patients with

lupus may prevent them from planning for future events or committing themselves to social arrangements. Some of the clinical features like pain, athralgia, oral ulcers may also limit patients' appearance in public due to the altered physical appearance. In the French, American and British population, planning was one of the better scoring domains. This was contributed to their populations having lower disease activity than this population and thus better able to carry out activities of daily life[51,,53,54].

Emotional health, though it had a poor score (61.3, SD 21.5), was one of the higher scoring domains. The possible explanation for this could be because most of the patients were married and the support from the spouse could have contributed to better emotional health. Also for the single people their immediate family could have still provided them with the emotional support needed to handle their condition. This was replicated in the American cohort that scored lower in emotional health, probably due to more physical pain that directly affects emotional health. The French and British scored better. Possible reasons are due to their longer duration of illness (9.4 years,9.4yrs respectively) the patients had adapted to their disease emotionally and also had milder disease than our population.

The domain concerning burden to others was our third highest scoring domain (58.9 SD 38.2). this This poor score could be attributed to the fact that most patients likely still had active disease especially those with duration of just a few monthssince diagnosis and had to rely on other people for help with their daily activities. However , even with a duration of illness of 8.9 years and a low disease activity, the Mexicans still had a poor score in this domain suggesting that there could be other factors contributing to a poor score in this domain.

Pain also had a poor score of 56.6, followed by Physical health (54.0 SD 23.3). Again these patients had early disease that was probably still active. Pain and physical health are directly related because presence of pain will contribute greatly to a person's physical health. Considering that the clinical features most prevalent were arthritis and athralgia, present in 88.7% , this could have contributed to the poor scores in these two domains. The American population scored poorly in pain domain and attributed this to aging and the co-morbidities that come with age eg. Age related arthritis. In this study, the older population scored better in the Physical Health domain, again suggesting there may be different factors in the two populations.

Again having scored low in pain domain and physical health, it is not surprising that Intimate Relations had the lowest scores (41.1 SD 38.4). This may have been due to the pain they were experiencing , the poor physical health and low body image and presence of fatigue, all of which can affect sexual relations. The Mexican population scored better and this could be attributed to their mild disease activity in most of their population.

Body image was one of the lowest scoring domains (47.1SD24.2). The presence of mouth ulcers in a large proportion of this population (62.9%) along with discoid rash, malar rash and

athritis may have adversely altered the body image of our patients due to the deformities associated with them.

Fatigue is one of the most common symptoms of lupus and can sometimes present on its own for years before diagnosis of lupus is finally made. Though the study did not look specifically for the presence of fatigue, many studies have found fatigue to be one of the most common and most debilitating feature in lupus. Robb-Nicholson found in his study a prevalence of 81%. He also found out that most of them had active disease.[22]

In the American study the most affected domain was fatigue and the least affected was intimate relationships, however, they thought it could be because of the sensitive nature of the questions because the patients scored low points in all other domains[51]
The British had relatively higher scores in all domains. This could have been because of the longer duration of the disease in the population and therefore their disease was better controlled.[54]

While there are no specific guidelines on the management of lupus, most patients are put on hydroxychloroquine as the backbone drug (LUMINA). The most common drug used was prednisone with majority (74.2%) being on it. This was followed by HCQ (69.4%) then NSAIDS (54.8%). Active disease is treated by prednisone and therefore majority of the patients probably had active disease. This could also be because of limited knowledge on lupus, of the clinicians diagnosing the patients and prescribing the drugs.

Azathioprine, Methotrexate(MTX) , Mycophenolate mofetil(MMF) and cyclosporine are used for organ specific disease and the fact that few patients were on them may reflect the fact that few had organ specific disease , or may reflect the limited knowledge of the primary physicians prescribing these medications. It is also important to note that drugs like MMF and Azathioprine are also used less frequently due to their cost with some patients being unable to afford them. Of note is that the 7(11.3%) patients using CCB were using them for HTN and not for Reynaud's phenomenon.

There was no correlation between HRQOL and the use of drugs.

Positive correlation was found when HRQOL was compared with age in the domains of Burden to others, Emotional health and Fatigue. Scores in these domains increased with advance in age. The American study found that advance in age correlated negatively with these domains[51]. A possible explanation for this could be emotional health improves in the older patients with lupus because they have had longer duration of illness therefore they have more stable disease. It could also be because they may have learnt coping mechanisms by then, that better help them accept and cope with their disease. Accepting and learning to cope may also have contributed to them being less of a burden to others.

However a different study that looks specifically at this correlation to find out which factors directly affect these domains would be warranted to better explain these findings. There was no association between HRQOL and duration since diagnosis. Gladman,[55] also reported a lack of association between HRQOL and disease duration. Jolly also found no correlation in his population in the U.S.[51]

10. CONCLUSION

This study demonstrates that the HRQOL of lupus patients attending clinic in Kenyatta National Hospital is poor, with the diasease greatly affecting both physical and psychological aspects of the patients' lives. The older patients were found to have less fatigue, better physical health and emotional health. There was no correlation between HRQOL and duration of illness and no correlation with the drugs used.

11. LIMITATIONS

HRQOL is dynamic and the cross sectional design of this study meant that it was not possible to measure any changes that may have occurred over time. The small sample size also made it impossible to do some of the correlation analysis e.g. for gender and some of the medications used.

12. RECOMMENDATIONS

As it is clear our population has an overall poor HRQoL.Measures that would help in improving their quality of life should be evaluated and implemented.

It would also be useful to do a longitudinal study that will be able to detect any changes in HRQOL in the same population.

It would also be prudent to do a disease severity study and see if there is any correlation with HRQOL in this population.

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APPENDIX 1 . DATA COLLECTION FORM

A) DEMOGRAPHIC INFORMATION

i) Study no

ii) Date of birth

iii) Gender 1 male ____ 2 female____

iv) Level of education

i. Primary b.Secondary c. Tertiary i Degree ii diploma

v) marital status

a. single b.married c.divorced` d. separated

B) DATE AT DIAGNOSIS

AGE AT DIAGNOSIS

DURATION OF ILLNESS

C) CLINICAL FEATURES OF SLE

CLASSIFICATION CRITERIA	**N**
MALAR RASH	
DISCOID RASH	
PHOTOSENSITIVITY	
ORAL ULCERS	
SEROSITIS	
ATHRITIS/ATHRALGIA	
CNS	

D) DRUGS

	YES	NO
i) Prednisone		
ii) Methylprednisone		
iii) NSAIDS		
iv) Hydroxychloroquine		
v) Calcium channel blockers		
vi) Methotrexate		
vii) Cyclosporine		
viii) Balimumab		
ix) Mycophenolate mofetil		
x) azathioprine		

G)LUPUS QOL SCORES

DOMAIN	TOTAL SCORE	AVERAGE SCORE
PYSICAL HEALTH		
PAIN		
PLANNING		
INTIMATE RELATIONSHIP		
BURDEN TO OTHERS		
EMOTIONAL HEALTH		
BODY IMAGE		
FATIGUE		

APPENDIX 2. STATEMENT OF INFORMATION FORM

Evaluation of quality of life of patients with SLE attending Kenyatta national hospital

STATEMENT OF INFORMATION FOR PATIENTS PARTICIPATING IN THE STUDY

I, Dr Jackline Odhiambo, a post graduate student in Internal Medicine at the University of Nairobi, would like to introduce you to a study I will be under taking entitled Evaluation of quality of life of patients with SLE attending Kenyatta national hospital**.**

The study will involve assessment of the quality of life of the SLE patients in our population.

Procedure

You are being asked to participate in a study that will take 25 to 40 minutes. If you agree to participate, the study will involve counseling that seeks to find out what you know about lupus and its treatment and clear any misconceptions you may have about the disease. With your permission I will then go to your medical records and get information i.e: your age, duration of illness and your last prescription.

I will then do a physical exam to look for any clinical features of lupus that you may have. I will then give you the LUPUS-QOL questionnaire to fill.

All the information provided will remain confidential. A copy of the results will be forwarded to your hospital file to assist in your continuous care. The information from you will not be used in any other way.

Part of the discomfort you may experience would be being asked to answer potentially embarrassing questions. The study will also require you to spend some extra time in the hospital.

The main benefit is that assessing your quality of life ill enable us to manage you better in the clinic.

Your participation in this study will be voluntary. You do not have to participate. If you choose to participate, but prefer not to answer specific questions, you are free to do so; however this limits the accuracy of the assessment. You are also free to withdraw from the study at any time and this will not affect your care or treatment in any way. You are free to ask questions before signing the consent form.

The purpose of the consent form is to request your permission to carry out this process. Should you agree, you will be required to sign the consent form.

If at any time you need to contact me, my contacts are below. You can also contact the KNH/UON ERC

Thank you for your cooperation,

Sincerely

DR. Jackline L.A. Odhiambo

Tel no. 0722806122

KNH/UON ERC no. +2542726300-19 / uonknh_erc@uonbi.ac.ke

APPENDIX 3 . CONSENT FORM.

I agree to take part in the study entitled 'Evaluation of Quality of Life of ambulatory patients attending Rheumattology clinic in KNH'.

I understand that the process will involve extracting information from my file that pertains to my disease. I also agree to a full physical examination to look for features of lupus that I may have.

I will then be given a questionnaire i.e. LUPUS-QOL questionnaire to fill in.

My participation in this study is voluntary. I do not have to participate. If I choose to participate, but prefer not to answer specific questions, I am free to do so; however this limits the accuracy of the assessment. I am also free to withdraw from the study at any time and this will not affect my care or treatment in any way. I am free to ask questions before signing the consent form.

If I have any enquiries during the course of the study, you may contact DR JACKLINE L.A. ODHIAMBO on mobile 0722806122

Name _____

Age_____

Tel no._____

Signature_____

Witness

Name _____

Age _____

Tel no. _____

Signature _____

Investigator's statement;

I, the investigator have educated the research participant on the purpose and implications of this study

Signed _____ Date _____

APPENDIX 4. STATEMENT OF INORMATION FOR MINORS

I Dr Jackline Odhiambo, a post graduate student in Internal Medicine at the University of Nairobi, would like to introduce you to a study I will be under taking entitled Evaluation of quality of life of patients with SLE attending Kenyatta national hospital**.**

The study will involve assessment of the quality of life of the SLE patients in our population.

Procedure

You are being asked to participate in a study that will take 25 to 40 minutes. If you agree to participate, the study will involve counseling that seeks to find out what you know about lupus and its treatment and clear any misconceptions you may have about the disease. With your permission I will then go to your medical records and get information i.e: your age, duration of illness and your last prescription.

I will then do a physical exam to look for any clinical features of lupus that you may have. I will then give you the LUPUS-QOL questionnaire to fill.

All the information provided will remain confidential. A copy of the results will be forwarded to your hospital file to assist in your continuous care. The information from you will not be used in any other way.

You can can choose to answer the questions with or without your guardians presence. Should you choose to answer your one, your answers will remain confidential and will not be given to a third party without your consent.

Part of the discomfort you may experience would be being asked to answer potentially embarrassing questions. The study will also require you to spend some extra time in the hospital.

The main benefit is that assessing your quality of life ill enable us to manage you better in the clinic.

Your participation in this study will be voluntary. You do not have to participate. If you choose to participate, but prefer not to answer specific questions, you are free to do so; however this limits the accuracy of the assessment. You are also free to withdraw from the study at any time and this will not affect your care or treatment in any way. You are free to ask questions before signing the consent form.

The purpose of the consent form is to request your permission to carry out this process. Should you agree, you will be required to sign the consent form.

If at any time you need to contact me, my contacts are below. You can also contact the KNH/UON ERC

Thank you for your cooperation,

Sincerely

DR. Jackline L.A. Odhiambo

Tel no. 0722806122

KNH/UON ERC no. +2542726300-19 / uonknh_erc@uonbi.ac.ke

APPENDIX 5 : ASSENT FORM FOR MINORS

Names _____

Age _____

Number _____

Name of guardian_____

Number_____

I agree to take part in the study entitled 'Evaluation of Quality of Life of ambulatory patients attending Rheumattology clinic in KNH'.

I understand that the process will involve extracting information from my file that pertains to my disease. I also agree to a full physical examination to look for features of lupus that I may have.

I will then be given a questionnaire i.e. LUPUS-QOL questionnaire to fill in.

My participation in this study is voluntary. I do not have to participate. If I choose to participate, but prefer not to answer specific questions, I am free to do so; however this limits the accuracy of the assessment. I am also free to withdraw from the study at any time and this will not affect my care or treatment in any way. I am free to ask questions before signing the consent form. The information I gave will remain confidential unless I consent for it to be revealed to a third party to be

If I have any enquiries during the course of the study, I may contact DR JACKLINE L.A. ODHIAMBO on mobile 0722806122

Name of guardian _____

Tel no._____

Signature_____

Witness

Name _____

Age _____

Tel no. _____

Investigator's statement;

I, the investigator have educated the research participant on the purpose and implications of this study

Signed ———————————————— Date ————————————————

APPENDIX 6: LUPUS QOL QUESTIONNAIRE

LupusQoL Questionnaire

The following questionnaire is designed to find out how SLE affects your life. **Read** each statement and then circle the response, which is **closest to how you feel**. Please try to answer all the questions as honestly as you can.

How often over the last 4 weeks

1. Because of my Lupus I need help to do heavy physical jobs such as digging the garden, painting and/or decorating, moving furniture

All of the time most of the time a good bit of the time occasionally never

2. Because of my Lupus I need help to do moderate physical jobs such as vacuuming, ironing, shopping, cleaning the bathroom

All of the time most of the time a good bit of the time occasionally never

3. Because of my Lupus I need help to do light physical jobs such as cooking/preparing meals, opening jars, dusting, combing my hair or attending to personal hygiene

All of the time most of the time a good bit of the time occasionally never

4. Because of my Lupus I am unable to perform everyday tasks such as my job, childcare, housework as well as I would like to

All of the time most of the time a good bit of the time occasionally never

5. Because of my Lupus I have difficulty climbing stairs

All of the time most of the time a good bit of the time occasionally never

6. Because of my Lupus I have lost some independence and am reliant on others

All of the time most of the time a good bit of the time occasionally never

7. I have to do things at a slower pace because of my Lupus

All of the time most of the time a good bit of the time occasionally never

8. Because of my Lupus my SLEep pattern is disturbed

All of the time most of the time a good bit of the time occasionally never

How often over the last 4 weeks

9. I am prevented from performing activities the way I would like to because of pain due to Lupus

All of the time most of the time a good bit of the time occasionally never

10. Because of my Lupus, the pain I experience interferes with the quality of my SLEep

All of the time most of the time a good bit of the time occasionally never

11. The pain due to my Lupus is so severe that it limits my mobility

All of the time most of the time a good bit of the time occasionally never

12. Because of my Lupus I avoid planning to attend events in the future

All of the time most of the time a good bit of the time occasionally never

13. Because of the unpredictability of my Lupus I am unable to organise my life efficiently

All of the time most of the time a good bit of the time occasionally never

14. My Lupus varies from day to day which makes it difficult for me to commit myself to social arrangements

All of the time most of the time a good bit of the time occasionally never

15. Because of the pain I experience due to Lupus I am less interested in a sexual relationship
All of the time most of the time a good bit of the time occasionally never not applicable
16. Because of my Lupus I am not interested in sex
All of the time most of the time a good bit of the time occasionally never not applicable

17. I am concerned that my Lupus is stressful for those who are close to me
All of the time most of the time a good bit of the time occasionally never
18. Because of my Lupus I am concerned that I cause worry to those who are close to me
All of the time most of the time a good bit of the time occasionally never
19. Because of my Lupus I feel that I am a burden to my friends and/or family
All of the time most of the time a good bit of the time occasionally never

Over the past 4 weeks I have found my Lupus makes me
20. Resentful
All of the time most of the time a good bit of the time occasionally never
21. So fed up nothing can cheer me up
All of the time most of the time a good bit of the time occasionally never
22. Sad
All of the time most of the time a good bit of the time occasionally never
23. Anxious
All of the time most of the time a good bit of the time occasionally never
24. Worried
All of the time most of the time a good bit of the time occasionally never
25. Lacking in self-confidence
All of the time most of the time a good bit of the time occasionally never

How often over the past 4 weeks
26. My physical appearance due to Lupus interferes with my enjoyment of life
All of the time most of the time a good bit of the time occasionally never

27. Because of my Lupus, my appearance (e.g. rash, weight gain/loss) makes me avoid social situations
All of the time most of the time a good bit of the time occasionally
never not applicable
28. Lupus related skin rashes make me feel less attractive
All of the time most of the time a good bit of the time occasionally
Never not applicable

How often over the past 4 weeks
29. The hair loss I have experienced because of my Lupus makes me feel less attractive
All of the time most of the time a good bit of the time occasionally
never not applicable

30. The weight gain I have experienced because of my Lupus treatment makes me feel less attractive

All of the time most of the time a good bit of the time occasionally never not applicable

31. Because of my Lupus I cannot concentrate for long periods of time

All of the time most of the time a good bit of the time occasionally never

32. Because of my Lupus I feel worn out and sluggish

All of the time most of the time a good bit of the time occasionally never

33. Because of my Lupus I need to have early nights

All of the time most of the time a good bit of the time occasionally never

34. Because of my Lupus I am often exhausted in the morning

All of the time most of the time a good bit of the time occasionally never

Please feel free to make any additional comments.

_____

_____

_____

_____

Please check that you have answered each question

Thank you, for completing this questionnaire

.