Original Article

Determinants of Eye Disorders in Patients with Rheumatoid Arthritis and Systemic Lupus Erythematosus in a Tertiary Hospital in Northern Nigeria

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Abstract

Objectives: To investigate the determinants of eye disorders in patients with rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE) in a Tertiary Hospital in Northern Nigeria. **Methods:** This hospital-based study was conducted among patients with RA and SLE. Information was obtained on patients' socio-demographics, type of rheumatic disease, disease duration, activity, and prescribed medications. RAPID 3 was used among both RA and SLE patients to measure and classify disease activity as: >12 = high; 6.1–12 = moderate; 3.1–6 = low; <3= remission. Each patient had detailed ocular examination. Statistical significance was set at $P < 0.05$. **Results:** The female:male ratio was 4.3:1 for RA and all SLE patients were females. Eye disorders were present in 42% of all patients, the most common being dry eyes (38%), refractive errors (18%), and cataracts (16%). The least findings were corneal opacities (2%) and lateral rectus palsy (2%). Mean duration of disease in years was significantly higher among RA patient that had eye disorders (7.23 ± 3.44) than those without (2.23 ± 1.23) ($P < 0.001$). It was also higher among SLE patients with eye disorders (6.73 ± 3.93) than those without (2.13 ± 1.06) ($P < 0.001$). Most RA patients with eye disorders had moderate [21 (28%)] to severe [8 (11%)] disease activity whereas majority of patients without eye disorders had low activity [16 (22%)] and near remission [26 (35%)] ($P < 0.001$). Most SLE patients with eye disorders had moderate [9 (35%)] to severe [1 (4%)] disease activity whereas majority of patients without eye disorders had low activity [3 (12%)] and near remission [12 (46%)]. **Conclusion:** Eye disorders are common among RA and SLE patients, and are influenced by longer disease duration, higher disease activity, and older age. Gender and drug therapy were not found to influence the presence of eye disorders. Eye examination should be done on all RA and SLE patients at regular intervals.

keywords: eye disorders, rheumatoid arthritis, systemic lupus erythematosus

Introduction

Rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE) form part of a spectrum of rheumatic diseases, a varied group of chronic disorders, that are associated with the presence of chronic inflammation, involving structures of the musculoskeletal system, blood vessels, and other tissues.[1] Ophthalmic manifestations are common,[2,3] and may have diagnostic and prognostic implications.[4] Some ophthalmic manifestations present before systemic manifestations of the disease, others present during the active stage of the disease whereas others are due to prolonged disease and/or medications used.[3,5] Longer disease duration has been associated with ophthalmic manifestation in RA.[6-8] The mean duration of RA in patients with ophthalmic manifestations in a study in India was found to be 5.4 ± 2.7 years whereas those without ophthalmic mmanifestations was 2.1 ± 1.6 years.[7] Similarly, Aboud *et al*.[8] in a study in Egypt found that RA patients with disease duration of >5 years had a 64.2%

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finding of ophthalmic manifestation compared to a frequency of 9.1% in patients with <5 years of disease duration. Patients with vision threatening manifestations such as peripheral ulcerative keratitis (PUK) were observed to have a longer mean disease duration of 10.5 ± 3.1 years.[7]

In SLE, ophthalmic manifestations may precede systemic disease[9] and hence correlating disease duration in relation to ophthalmic manifestations may be difficult. The measurement of disease activity using validated activity index helps in patient monitoring and provides a reliable basis for therapeutic intervention. High disease activity was found to be associated with the presence of eye disorders in patients with SLE.[10] Medications employed in the management of RA and SLE may be associated with increased risk of ophthalmic morbidity. This study sought to elucidate the relationship between disease duration, activity, and medications used and the presence of eye disorders among patients with RA and SLE in a tertiary health center in Northern Nigeria.

Materials and Methods

This hospital based cross-sectional study was conducted between July and December 2020 in the Rheumatology and Eye clinics of Ahmadu Bello University Teaching Hospital, Zaria (ABUTH). Ethical approval for the study was obtained from the Health Research Ethical Committee (HREC) of the Institution, (ABUTHZ/HREC/W21/2019). The study observed the guidelines of the Helsinki Declaration on Human research. Written informed consent for the study was obtained from each participating patient prior to enrollment.

All consenting adult patients aged 18 years and above diagnosed with RA or SLE attending the rheumatology clinic irrespective of gender, duration or severity of disease, and the presence or absence of ocular symptoms were invited to participate in the study. Patients with uncontrolled systemic conditions such as, diabetes or hypertension, patients with infectious diseases accounting for, or predisposing to ocular findings, such as active tuberculosis and human immunodeficiency virus and patients who did not give their consent were excluded from the study.

Using a standard normal deviate of 1.96 (95% Confidence Interval), prevalence of 46% from a previous study,[8,9] a study population of less than 10,000 and an attrition rate of 10%, a minimum sample size of 100 patients was estimated. Convenience sampling technique was used to select study participants. Participants were enrolled into the study as they presented to the clinic. Each week, all new and follow up patients with RA and SLE attending the rheumatology clinic were enrolled into the study and assigned a unique study identification number. Extra care was taken to avoid duplication of participants.

A semi structured pre-tested (in the eye clinic) interviewer administered questionnaire was used to collect patients' biodata and sociodemographic characteristics, present and past ocular history, medical history of systemic disease, and family history of rheumatic disease. The type of rheumatic disease, disease duration, and details of medications patient was on were also obtained from patient's hospital' medical records, and assessment of disease activity based on a standard measurement tool; routine assessment of Patient Index Data 3 (RAPID3) was also done. Patients had complete ophthalmic examination in the following sequence: visual acuity testing, refraction, color vision test, central vision test, testing for dry eye using tear break up time (TBUT) and Schirmer test, anterior segment examination, applanation tonometry, gonioscopy, and then dilated fundal examination with +78D lens.

Visual acuity testing

Visual acuity testing was done by an ophthalmic nurse. Each eye was tested separately using a Snellen chart (E-chart for non-literate patients) at 6 m. A pin hole was used where necessary, and spectacles if available. Near vision testing was done using the handheld snellen near vision chart at 40 cm.

Color vision test

Color vision test was conducted in a well-lit room with the Ishihara test plates. The plates were held 75 cm from the patient at right angle to the line of vision. Each patient was tested with 17 plates. Normal literate patients are expected to identify the number on each plate within 3 seconds whereas normal non-literate patients are expected to trace the winding lines within 10 seconds. Correct identification or tracing of 10 plates or more indicates normal color vision whereas defective color vision is identification of seven plates or less.

Central vision test

Central vision was tested using the standard Amsler's chart. The patient was seated comfortably in a well illuminated room. The procedure was explained to the patient. Each eye was tested separately. Patients were instructed to wear their near reading correction or were provided with one if necessary.

The Amsler's chart was held at 30 cm away from the eye to be tested while the other eye was occluded. The patient was instructed to focus on the dot in the center of the grid. The patient was then asked to report any lines that are blurred, wavy, distorted, or missing. The absence of any defects was taken as normal.

Refraction

Refraction was carried out on patients with a visual acuity of 6/9 or worse by the optometrist. The procedure was explained to the patient. At a working distance of 66 cm, each eye was refracted using streak retinoscope. Objective refraction followed by subjective refinement was done. The prescription was recorded and given to the patient to fix spectacles.

Applanation tonometry

The procedure was explained to each patient. The prism head of handheld Perkins applanation tonometer (Clement Clark international, Model MK2) was sterilized with 0.5% sodium hypochlorite solution. A drop (or more, if required) of topical anesthetic agent was instilled into each eye with a drop of 2% fluorescein. The patient was seated comfortably and instructed to look straight ahead at a target. With the fore head rest of the tonometer in position, and the prism head in contact with the center of the cornea, the intra ocular pressure was measured by turning the thumb wheel. The measurement was taken at the point when the inner edges of the semi-circles met (by observing through the finder eye piece).

Testing for dry eye (using Schirmer strip and tear break up time)

Tear break up time (TBUT)

The procedure was explained to each patient. A drop of 2% fluorescein was instilled into the eye to be examined. The patient was instructed to blink several times to ensure even distribution of fluorescein. Using a slit lamp biomicroscope with a cobalt blue filter, the patient was instructed to look straight ahead without blinking. The TBUT is the number of seconds (measured with a stop watch) between the last blink and the appearance of the first dry spot in the tear film. A TBUT of 10 seconds or more was taken as normal.[11]

Schirmer test

The procedure was explained to the patient. A drop of topical anesthetic agent was instilled into each eye. Excess tears were wiped off using cotton wool. Schirmer strip (folded at the 5 mm at the upper end) was gently placed at the junction between the inner 2/3 and outer 1/3 of the lower eye lid. Patient was instructed to gently close the eyes. The strip was removed after 5 minutes and the amount of wetting read. Wetting of less than 6 mm was taken as abnormal.[11]

Gonioscopy

The procedure was explained to each patient. Goldmann 4 mirror gonioscopy lens were sterilized with 0.5% sodium hypochlorite solution, rinsed with clean water and dried with cotton wool. A drop of topical anesthetic agent was instilled into the eye to be examined. The patient seated comfortably at the slit lamp and the gonioscopy lens was gently applied on the eye. The patient was instructed to look straight ahead. The anterior chamber angles visualized were graded using Schaffer grading system.

Slit lamp biomicroscopy and dilated fundoscopic examination with +78D fundus lens

The procedure was explained to each patient. A detailed anterior segment examination was carried out on each eye. A drop of dilating agent (0.5% tropicamide + 2.5% phenylephrine) was instilled. When required, additional drops were instilled to achieve adequate dilatation. With an adequately dilated eye, the patient was seated comfortably at the slit lamp. Each eye was examined for presence of posterior segment changes, such as cotton wool spots, retinal hemorrhages, perivascular sheathing, retinal exudates, arteriolar attenuation, venous tortuosity, neovascularization, papillitis, pallor, and cupping of the optic nerve head and macular changes. Findings were recorded. Patients with abnormal findings had one or more investigations of central visual fields, anterior segment photography, fundus photography, Central visual fields using Optopol PTS 920 machine and Optical Coherence Tomography (OCT) using Zeiss stratus OCT, Model 3000. All examinations and tests apart from visual acuity and refraction were done by a single ophthalmologist.

Disease activity measurement: The Routine Assessment of Patient Index Data 3 (RAPID3) was used to measure disease activity since it has been found to be accurate, useful, and feasible for use in clinic setting and can be used as a measure for both RA and SLE[12,13] and it's similar to established measures in its predictive ability.[13] RAPID3 is a pooled index of the three patient-reported American College of Rheumatology rheumatoid arthritis (RA) Core Data Set measures: function, pain, and patient global estimate of status. Each of the three individual measures is scored 0 to 10, for a total of 30. Disease severity was classified on the basis of RAPID3 scores as: >12 = high; 6.1–12 = moderate; 3.1–6 = low; <3 = remission.[13]

Data Handling/Statistical analysis

Data were checked for consistency and completeness and entered into statistical package for social sciences (SPSS) version 25 (IBM Corp., Armonk, NY, USA) and analyzed.

For descriptive statistics, frequencies and percentages were used for qualitative variables, while mean and standard deviation were used for quantitative variables. These variables were categorized where necessary and presented in tables and graphs. For analytical statistics, Chi-square, Fisher exact test, or *t* test were used as appropriate to compare for association between variables and statistical significance was assessed at P value <0.05.

Results

A total of 100 patients, 74 of which had RA and 26 SLE were recruited for the study. Of the recruited patients, 86% were females and 14% were males. Majority of the study participants are females [86, (86%)], of Hausa ethnic group [54, (54%)] and had tertiary education [45, (45%)]. The most frequent age group affected was 21 to 40 years, followed by the age group, 41 to 60 years.

The demographic characteristics of the patients are shown in Table 1. All SLE patients were females, with a mean age of 37.08 ± 13.71, while majority of the RA patients were females giving female to male ratio of 4.3:1 and a mean age of 46.45 ± 15.19. These observed differences were statistically significant (mean age $P = 0.007$ and gender $P = 0.017$).

Table 1: Socio demographic characteristics of RA and SLE patients

Variable	Rheumatic disease		X^2/FET/*t* test	*P*-value
	RA (*n* = 74)	SLE (*n* = 26)		
Age (years) Mean ± SD	46.45 ± 15.19	37.08 ± 13.71	2.771***	*0.007**
Gender				
Female	60 (81.1)	26 (100.0)	5.720****	*0.017**
Male	14 (18.9)	0		
Ethnicity				
Hausa	36 (48.6)	18 (69.2)	4.048**	*0.373*
Fulani	13 (17.6)	2 (7.7)		
Yoruba	4 (5.4)	2 (7.7)		
Igbo	3 (4.1)	0		
Others	18 (24.3)	4 (15.4)		
Educational level				
No formal education	19 (25.7)	2 (7.7)	7.861**	*0.041**
Primary	5 (6.8)	2 (7.7)		
Secondary	15 (20.2)	12 (46.1)		
Tertiary	35 (47.3)	10 (38.5)		
Occupation				
Unemployed	23 (31.0)	9 (34.7)	3.388**	*0.655*
Student	10 (13.5)	6 (23.1)		
Civil servant	15 (20.3)	6 (23.1)		
Business	11 (14.9)	1 (3.8)		
Artisan	4 (5.4)	1 (3.8)		
Others	11 (14.9)	3 (11.5)		

*P-value significant at <0.05; **FET: Fisher exact test, *** t test; ****Chi-square.

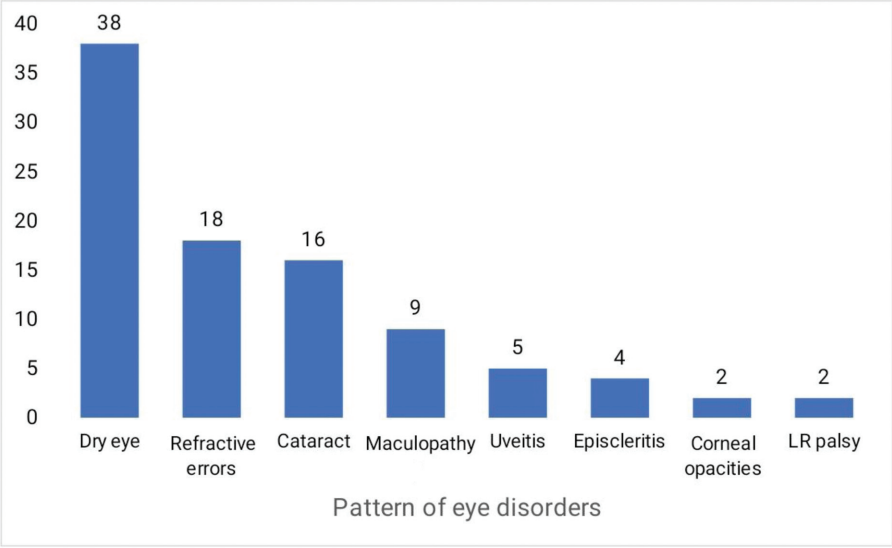

Figure 1: Bar chart showing pattern of eye disorders in RA and SLE patients.

Thirty-six (48.6%) of RA and 18 (69.2%) of SLE patients were Hausas. This observed difference was not statistically significant ($P = 0.373$). Majority of the patients in the RA group had tertiary education [35(47.3%)] while those in the SLE group had secondary education [12, (46.2%)]. This observed difference was statistically significant ($P = 0.041$).

The prevalence of eye disorders in all patients was 42% (41.9% and 42.3% among RA and SLE patients respectively).

Majority of the patients had Dry eyes (38%), followed by refractive errors (18%) and cataracts (16%). The least findings were corneal opacities and lateral rectus palsy as shown in Figure 1.

Mean disease duration among RA and SLE patients with and without eye disorders is shown in Table 2. The observed difference in disease duration of RA and SLE patients with and without eye disorders was statistically significant ($P < 0.001$).

Majority of RA patients with eye disorders had moderate [21 (28%)] to severe [8 (11%)] disease activity whereas majority of patients without eye disorders had low activity [16 (22%)] and near remission [26 (35%)]. This observed difference was statistically significant ($P < 0.001$) as shown in Figure 2.

Majority of SLE patients with eye disorders had moderate [9 (35%)] to severe [1 (4%)] disease activity whereas majority of patients without eye disorders had low activity [3 (12%)] and near remission [12 (46%)]. This observed difference was statistically significant ($P < 0.001$) as shown in Figure 3.

The medications taken by both RA and SLE patients are shown in Table 3, the most predominant medication being Hydroxychloroquine (HCQ).

Tables 4 and 5 show no statistically significant difference in the various medications taken by RA and SLE patients with and without eye disorders respectively.

Table 6 shows no statistically significant difference in the various medications taken by both RA and SLE patients with and without eye disorders.

Discussion

This study assessed the relationship between the presence of eye disorders and disease duration, activity and medication used among patients with RA and SLE in Ahmadu Bello University Teaching Hospital, Zaria and found that the presence of eye disorders in both RA and SLE was influenced by a longer disease duration and a higher disease activity. No relationship between eye disorders and drug therapy was established.

The female to male ratio were 4.3:1in the RA patients, with all SLE patients being females. This study found the female gender more affected as observed in other studies by Sen *et al*.,[2] and Cho.[3] The finding of preponderance of female patients in RA (81.1%) and SLE (100%) is in keeping with the nature of autoimmune diseases. Various reasons have been given for the female preponderance in autoimmune disease, these include: female reproductive hormones, genetic factors, and environmental exposures that may be culturally or occupationally determined.[2] Additionally, differences in

Table 2: Mean disease duration of RA and SLE patients with and without eye disorders

	Eye disorder		*t* test	*P*-value
Rheumatoid arthritis	**Absent ($n = 43$)**	**Present ($n = 31$)**		
Disease duration Mean ± SD (years)	2.23 ± 1.23	7.23 ± 3.44	8.784	*<0.001**
Systemic lupus erythematosus	Absent ($n = 15$)	Present ($n = 11$)		
Disease duration Mean ± SD (years)	2.13 ± 1.06	6.73 ± 3.93	4.349	*<0.001**

**P*-value significant at <0.05.

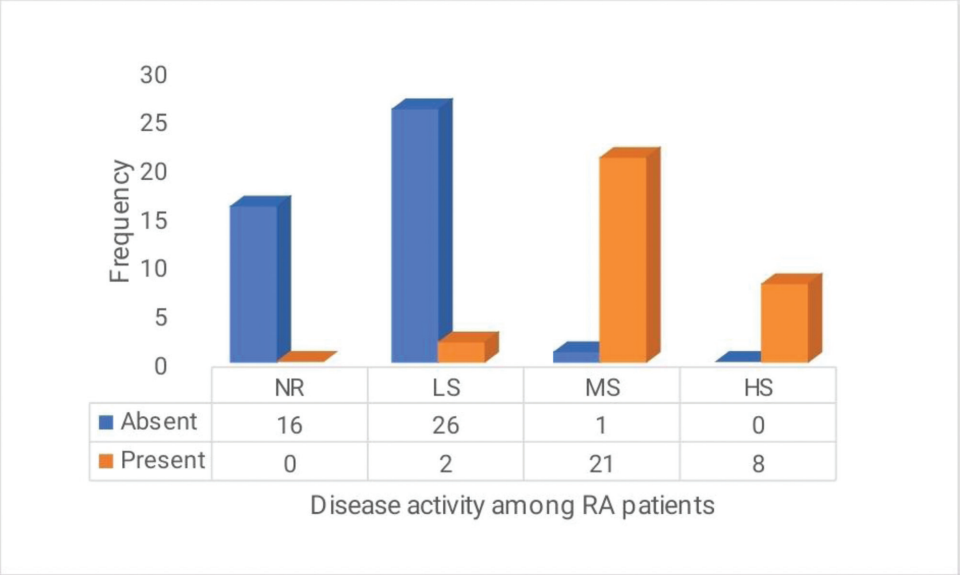

Figure 2: Disease activity in RA patients. Chi-square = 62.450, *P*-value ≤ 0.001*. HS, high severity; LS, low severity; MS, moderate severity; NR, near remission.

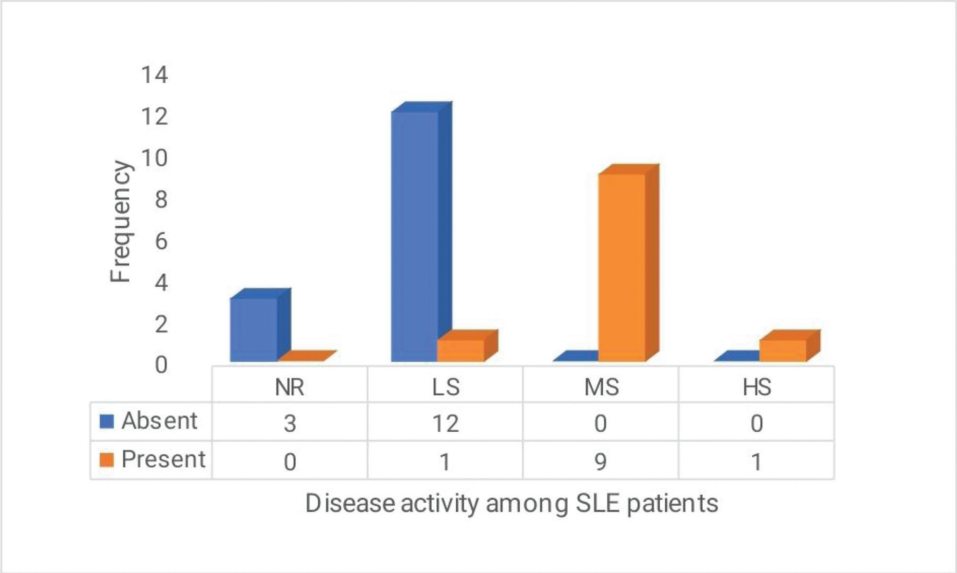

Figure 3: Disease activity in SLE patients. Chi square = 62.450, *P*-value ≤ 0.001*. HS, high severity; LS, low severity; MS, moderate severity; NR, near remission.

Table 3: Medications taken by RA and SLE patients

Medications	*N*	Rheumatic disease		Chi-square	*P*-value
		RA (%)	SLE (%)		
HCQ	92	73(79.3)	19(20.7)	17.094	*<0.001**
MTX	42	41(97.6)	1(2.4)	20.996	*<0.001**
AZA	38	17(44.7)	21(55.3)	27.279	*<0.001**
Pred	31	22(71.0)	9(29.0)	0.215	*0.643*
MMF	2	0	2(100.0)	5.808	*0.016**
SLZ	2	2(100.0)	0	0.717	*0.397*

Some patients are on multiple medications; percentages are not expected to add up to 100%. AZA, azathioprine; HCQ, hydroxychloroquine; MMF, mycophenolate mofetil; MTX, methotrexate; Pred, prednisolone; SLZ, sulphasalazine. **P*-value significant at <0.05.

Table 4: Medications prescribed in RA patients with and without eye disorders

Medications	Eye disorder		Chi-square	*P*-value
	Absent *N* = 42 (%)	Present *N* = 31 (%)		
HCQ	42(57.5)	31(42.5)	0.731	*0.393*
MTX	23(56.1)	18(43.9)	0.153	*0.696*
AZA	10(58.8)	7(41.2)	0.005	*0.946*
Pred	12(54.5)	10(45.5)	0.163	*0.689*
MMF	0	0	-	-
SLZ	1(50.0)	1(50.0)	0.056	*0.814*

AZA, azathioprine; HCQ, hydroxychloroquine; MMF, mycophenolate mofetil; MTX, methotrexate; Pred, prednisolone; SLZ, sulphasalazine. **P*-value significant at <0.05.

health seeking behavior in female patients compared to males could also be a factor. Several studies have alluded to a better health seeking behavior amongst female patients compared to males.[14-16]

Table 5: Medications prescribed in SLE patients with and without eye disorders

Medications	Eye disorder		Chi-square	*P*-value
	Absent *n* = 15(%)	Present *n* = 11(%)		
HCQ	11(57.9)	8(42.1)	0.001	*0.973*
MTX	1(100.0)	0	0.763	*0.382*
AZA	13(61.9)	8(38.1)	0.794	*0.373*
Pred	5(55.6)	4(44.4)	0.026	*0.873*
MMF	0	2(100.0)	2.955	*0.086*
SLZ	0	0	–	–

AZA, azathioprine; HCQ, hydroxychloroquine; MMF, mycophenolate mofetil; MTX, methotrexate; Pred, prednisolone; SLZ, sulphasalazine. **P*-value significant at <0.05.

Table 6: Medications in RA and SLE patients with and without eye disorders

Medications	Eye disorder		Chi-square	*P*-value
	Absent *n* = 58(%)	Present *n* = 42(%)		
HCQ	53(57.6)	39(42.4)	0.072	*0.788*
MTX	24(57.1)	18(42.9)	0.022	*0.883*
AZA	23(60.5)	15(39.5)	0.161	*0.689*
Pred	17(54.8)	14(45.2)	0.184	*0.668*
MMF	0	2(100.0)	2.818	*0.093*
SLZ	1(50.0)	1(50.0)	0.054	*0.817*

AZA, azathioprine; HCQ, hydroxychloroquine; MMF, mycophenolate mofetil; MTX, methotrexate; Pred, prednisolone; SLZ, sulphasalazine. **P*-value significant at <0.05.

The mean age of all RA patients in this study was found to be 46.45 ± 15.19 years which is similar to several other studies.[6,8,17] Patients with eye disorders had a

significantly higher mean age of 52.19 ± 16.71 years as compared to those without eye disorders of 42.30 ± 13.14 years, similar to the findings of the study carried out by Akintayo *et al*.[6] in which patients with eye disorders had a mean age of 51.9 ± 13.5 years while those without eye disorders had a mean age of 44.0 ± 10.7 years. Older age and longer duration of disease have been found to be predictors of eye disorders in patients with RA.

The mean age of SLE patients studied was however lower than that of the RA patients at 37.08 ± 13.71 years with a range of 19 to 63 years which is similar to what was found in the study by Hussein *et al*.[18] with an age ranges of 18 to 61 years. The mean age of those with and without eye disorder among SLE patients was found to be lower than that of RA patients in this study. This difference may be due to the early onset of SLE in blacks.[19]

Longer disease duration has been found to be associated with eye disorders.[6-8] This study found that RA patients with eye disorders had a longer mean disease duration of 7.23 ± 3.44 years when compared to those without eye disorders of 2.33 ± 1.23 years. This difference was found to be statistically significant (P value < 0.001) and similar to findings of other studies.[6–8] This finding is not unexpected, given that RA and SLE are by nature chronic diseases; and accrual damage from chronic diseases are often a product of disease duration and its intensity.

In patients with SLE, this study found a statistically significant difference (P value < 0.001) in mean disease duration for patients with and without eye disorders at 6.73 ± 3.93 years as compared to 2.13 ± 1.06 years respectively. El Shareef *et al*.,[10] in their study also found similar results. Peponis *et al*.[9] in their study showed that eye disorders may precede systemic disease in SLE.

This study found that, both RA and SLE patients with eye disorders had moderate to high disease severity and those without eye disorders had low disease or in near remission. These values were found to be statistically significant in both conditions (P value < 0.001). A study of disease activity in RA patients by Aboud *et al*.[8] using Disease activity score 28 (DAS28) did not find any statistically significant difference between disease activity and eye disorders, however El Shareef *et al*.[10] found that the presence of eye disorders correlated with disease activity assessed using Systemic Lupus Erythematosus Disease Activity Index (SLEDAI). The difference in assessment tools may account for the difference in the findings.

Several classes of medications are used in the treatment of RA and SLE. These include Non-Steroidal Anti Inflammatory Drugs (NSAIDS), Corticosteroids, Disease Modifying Anti Rheumatic Drugs (DMARDs)/Immunomodulators, Biologic Disease modifying Anti Rheumatic Drugs (bDMARDs), Analgesics, Cytotoxics. Other medications used in SLE include Mycophenolate and Interferon antagonists. These medications are either prescribed alone or usually in combination.This study found that the most common medications prescribed in RA patients include HCQ, MTX, and prednisolone. Similarly, Akintayo *et al*.[6] found that the most patients were on prednisolone, MTX, and HCQ.

In SLE however, the most prescribed drugs were AZA, HCQ, and prednisolone. However, in a study by El Shareef *et al*.,[10] the most prescribed medications were Corticosteroid, Antimalarials, and azathioprine.

There were no patients on biologic Disease Modifying Anti rheumatic drugs (bDMARDs) in this study. This may be due to its high cost in Nigeria.

The type of medication prescribed for both SLE and RA patients in this study had no statistically significant difference with regards to presence or absence of eye disorders. A study by El Shareef *et al*.[10] found no correlation between retinal affection, dose, and duration of antimalarial drug. Akintayo *et al*.[6] also did not find any difference in the prevalence of eye disorders among patients on prednisolone and hydroxychloroquine and those who were not. Hydroxychloroquine is known to be much safer compared to chloroquine (CQ) as up to 95% of patients on CQ will develop some ocular complications compared to 10% of patients on Hydroxychloroquine.[6]

Limitations of the study include, being a hospital-based study, the results may not be a true reflection of the general population. The non-probability sampling technique used is also a limitation of the study.

In conclusion, this study assessed the relationship between disease duration, activity, medication used, and the presence of eye disorders among patients with RA and SLE attending Rheumatology clinic at Ahmadu Bello University Teaching Hospital, Zaria.

The presence of eye disorders was higher in patients with longer disease duration, higher disease activity, and older age (in RA only). Gender and drug therapy were not found to influence the presence of eye disorders. It is recommended that comprehensive eye examination be done on all RA and SLE patients at diagnosis, before commencement of medications, and periodically during follow ups. In addition, patients with eye complaints should also be referred promptly for evaluation by an ophthalmologist.

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Conflicts of interest

There are no conflicts of interest.

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