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Quality of Life in Sarcoidosis: Comparing the Impact of Ocular and Non-ocular Involvement of the Disease

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Abstract

Purpose—To compare the differences in vision and health-related quality of life (HRQOL) of individuals with ocular and non-ocular sarcoidosis; and to examine the impact of specific demographic and clinical factors on the noted differences.

Methods—A cross-sectional study using non-randomized prospective cohort was conducted at the National Eye Institute (protocol number: 06-EI-0239, NCT00379275) from August 31, 2006 until November 15, 2007. Each participant completed vision and HRQOL questionnaires, the Sarcoidosis Health Questionnaire (SHQ) and the National Eye Institute Visual Function Questionnaire (NEI-VFQ), along with a demographic/environmental exposure survey. Clinical data were collected through an ophthalmic exam as part of the research protocol.

Results—The study enrolled 75 biopsy-proven and 20 clinically presumed sarcoidosis participants which were divided into two cohorts, ocular (N = 60) and non-ocular groups (N = 35). The ocular group had significantly lower ($P < 0.01$) total NEI-VFQ scores compared to the non-ocular group. Multiple linear regression analysis showed that participants with ocular sarcoidosis who had an annual household income of < $50,000 ($P < 0.01$) had significantly lower total SHQ scores while participants with ocular sarcoidosis whose visual acuity was 20/100 or worse had significantly lower total NEI-VFQ scores ($P = 0.03$).

Conclusions—Ocular involvement impacts both overall and vision-related quality of life among sarcoidosis patients. Lower economic status appears to have a significant impact on the quality of life of sarcoidosis patients. Assessment of visual function and general health status provide pertinent information for individuals with sarcoidosis and should be included in their care to assess burden of their disease on their quality of life.

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Keywords

Health-related quality of life; Vision-related quality of life; Ocular sarcoidosis; Pulmonary sarcoidosis; Burden of disease

INTRODUCTION

Sarcoidosis is a chronic, progressive, multisystemic condition of unknown etiology that can involve pulmonary, cutaneous, and ocular systems.[1,2] Although its mortality rate is low, the chronic nature of the disease can be disabling both physically and mentally, especially to those with extrapulmonary involvement.[3,4] Current therapeutic regimens for sarcoidosis include various immunosuppressive agents that may alter the course of the disease and improve health outcomes but they carry significant side effects that may affect patients' daily activities and quality of life.[5–7]

Ocular sarcoidosis can present as a granulomatous uveitis,[5] which is noted in 20%–30% of cases,[8,9] and may be the initial manifestation of systemic disease.[10] Related complications from ocular sarcoidosis may include cataract, secondary glaucoma, retinal and optic nerve head neovascularization, cystoid macular edema, and/or retinal detachment.[8] Demographic factors such as advanced age, African American ethnicity, female gender, and chronic systemic disease; and clinical factors such as posterior segment involvement, peripheral punched out lesions, cystoid macular edema, and glaucoma have been associated with poor visual prognosis for individuals with ocular sarcoidosis.[11,12] Younger African American patients may be more likely to present with ocular sarcoidosis than Caucasians and may be more likely to have a less favorable clinical course.[13,14]

Several studies indicated that sarcoidosis patients may have a lower health-related quality of life compared to healthy controls and even individuals with chronic conditions such as rheumatoid arthritis.[3,15–17] However, information on quality of life among individuals with ocular sarcoidosis is still sparse. With this study, we aimed to assess vision and health related quality of life (HRQOL) and their relation to specific sociodemographic and clinical features among individuals with ocular and non-ocular sarcoidosis.

METHODS

The study protocol was reviewed and approved by the Institutional Review Board of the National Eye Institute (NEI), National Institutes of Health (NIH). The study's recruitment and data collection processes were designed to protect human subjects' privacy and confidentiality in accordance with the Department of Health and Human Services (DHHS) policy for protection of human research subjects.[18] This is a cross-sectional study of patients with sarcoidosis with and without ocular involvement that was done under a prospective observational research protocol (protocol number: 06-EI-0239, NCT00379275) that enrolled 95 participants from August 31, 2006 until November 15, 2007 at NEI. Each participant completed the vision-related quality of life questionnaire, the National Eye Institute Visual Function Questionnaire (NEI-VFQ), and the HRQOL questionnaire, the Sarcoidosis Health Questionnaire (SHQ), along with a demographic/environmental exposure survey. Clinical data were collected in a standard fashion under this protocol and included a complete ophthalmic examination and systemic evaluations as indicated. Inclusion criteria for this study were clinical diagnosis of sarcoidosis based on radiographic, hematologic, and ophthalmologic findings with or without a supporting histopathologic diagnosis, age 18 to 65 years old, able to understand and consent to participate in the study. A clinical diagnosis of sarcoidosis was based on presence of one radiographic or laboratory finding (ie, elevated

angiotension converting enzyme (ACE), presence of typical lung findings on chest imaging) and one clinical feature (ie, typical ocular involvement, change in pulmonary function tests). For participants with severe visual impairment a study coordinator was available to administer the questionnaire. Participants were excluded if they were recipients of organ transplantations or had active cancer as these were considered significant confounders or had cognitive deficits that prevented them from completing the questionnaires. All participants underwent several diagnostic examinations including pulmonary function testing, high resolution chest computed tomography (CT)/chest X-ray, anergy panel testing, serum ACE (Angiotensin Converting Enzyme), serum lysozyme, and ionized calcium levels. Physical examination consultations mostly from the pulmonary, dermatology, and neurology services were obtained as indicated.

Both SHQ and NEI-VFQ were administered by NIH-certified clinicians. All study participants completed both questionnaires upon arrival to the clinic prior to their ophthalmic examinations to avoid extraneous influences on their responses. The SHQ is a 29-item HRQOL questionnaire, developed by Cox et al., and was designed to measure three domains: daily functioning, physical functioning, and emotional functioning of individuals with sarcoidosis.19 The NEIVFQ is a 25-item vision-related QOL questionnaire that was utilized to assess 12 quality of life subscales: the individual's general health, general vision, near vision, distance vision, driving, peripheral vision, color vision, ocular pain, role difficulties, dependency, social functioning, and mental health.[20] Both SHQ and NEI-VFQ scores can range from 0–100, with lower scores indicating lower quality of life. It was estimated that each participant would take 10 to 20 minutes to complete the SHQ and 20 to 30 minutes to complete the NEI-VFQ. In addition, demographic information, income, and environmental exposures were obtained using the sociodemographic/environmental survey developed by the investigators. Medical history, ocular history, medications, history of biopsy for diagnosis, date of sarcoidosis diagnosis in which duration of disease was established, and date of onset of ocular sarcoidosis were collected at enrollment. Additional data were obtained from the review of medical records, which included ACE levels, carbon monoxide diffusion capacity (DLCO) results, chest radiographic (CXR/CT) findings, and systemic involvement of the disease. Patients with sarcoidosis were grouped into two cohorts: ocular and non-ocular. Ocular sarcoidosis was defined as any ocular involvement by the disease, including uveitis, optic neuritis, and sclerokeratitis with or without systemic involvement. Non-ocular was defined as systemic involvement with no ocular disease at baseline. Ocular manifestations obtained from the initial ophthalmologic examination were grouped as follows: anterior, intermediate, posterior or panuveitis in accordance with the Standardization of Uveitis Nomenclature (SUN) criteria.[21]

Statistical analyses of the data were conducted using the Statistical Analysis System (SAS) version 11 (SAS Institute Incorporated, Cary, NC). Descriptive statistics were calculated for the demographic (age, gender, race, income, consanguity, environmental exposures) and clinical characteristics (ACE levels, chest x-ray [CXR] results, diffusion lung capacity for carbon dioxide [DLCO], treatment, duration of disease) of all participants. Univariate two-sample *t*-tests were used to compare the means of total SHQ and total NEI-VFQ scores between ocular and non-ocular sarcoidosis cohorts, as well as individual SHQ domain and NEI-VFQ subscale scores. To test for the statistical significance of the differences in total SHQ and total NEI-VFQ scores between the two groups (ocular and non-ocular cohorts), multiple linear regression models were fitted, adjusting for the effects of age, race, gender, income, treatment, and duration of disease. In the ocular cohort, univariate, unadjusted Analysis of Variance (ANOVA) was applied to determine the impact of ocular factors (visual acuity, laterality of eye involvement, location and activity of uveitis) on the total SHQ and total NEI-VFQ scores. To select the "best" models for the total SHQ and total NEI-VFQ scores among all the combinations of demographic, clinical, and ophthalmologic

variables for the ocular group, we employed the Akaike's Information Criterion (AIC), a preferred criterion for model selection which takes into consideration goodness of fit and model complexity.[22] Association of demographic, clinical, and ophthalmologic characteristics with total SHQ and total NEI-VFQ scores were analyzed by fitting the selected multiple linear regression models for the ocular group. A two-tailed *p*-value of 0.05 was considered statistically significant.

RESULTS

A total of 110 individuals were approached to participate in the study. Two patients refused and 13 patients did not meet the inclusion criteria. The effective sample size was 95 and the participants were divided into two cohorts based on presence or absence of ocular involvement with sarcoidosis. The ocular cohort had 60 participants and the non-ocular cohort had 35 participants. All participants in both cohorts were seen for ocular examination at the NEI outpatient clinic. Table 1 summarizes the demographic and clinical characteristics including environmental exposures for the entire cohort. Participants' ages ranged from 22–65 years with a mean of 48.3 years. Seventy six percent (N = 72/95) were women, and 68% (N = 65/95) were African-Americans. These characteristics of the sample were consistent with previous epidemiological findings on sarcoidosis.5،23 The sociodemographic/environmental survey revealed that 53% (N = 50/95) had an annual household income equal to or below $50,000 and 15% (N = 14/95) less than $10,000 a year. Only 14% (N = 13/95) of participants reported sarcoidosis among blood relatives, both immediate (N = 4/95) and extended families (N = 9/95). Twenty-one percent (N = 20/95) of the participants reported exposure to tuberculosis and 35% (N = 33/95) to bedding materials.

A diagnosis of sarcoidosis was confirmed by tissue biopsy in 80% (N = 76/95) and 20% (N = 19/95) had a clinical diagnosis of sarcoidosis. In the entire cohort, ACE levels were elevated in 36% (N = 25/69), abnormalities on CXR/CT consistent with sarcoidosis (eg, lymphadenopathies, pulmonary infiltrates) were noted in 78% (N = 48/61) and DLCO was reduced ≤60% from the predicted in 21.2% (N = 7/33) of the participants. Forty-five percent of the entire cohort had disease duration of ≤5 years (range 2 months–42 years). Mean disease duration was 10.21 years for the entire cohort (10.28 years for the ocular and 10.1 years for the non-ocular cohort). Forty-four participants (46%) were not on any treatment for their sarcoidosis at the time of enrollment.

Table 1 describes the characteristics of the ocular cohort. Eighteen percent (N = 11/60) of the ocular participants had visual acuity worse than 20/100. All participants in the ocular group had uveitis: 17% (N = 10/60) anterior uveitis, 42% (N = 25/60) intermediate uveitis, 13% (N = 8/60) posterior uveitis, and 28% (N = 17/60) panuveitis. Eighty-two percent had bilateral involvement (N = 49/60) and 35% had active inflammation at enrollment (N = 21/60). Twenty percent of the ocular group participants (N = 12/60) were taking oral corticosteroids and 20% (N = 12/60) were taking some form of costicosteroid-sparing agent for their ocular sarcoidosis.

An unadjusted two-sample t-test showed no significant difference (with equal variances, $p = 0.441$) in the total SHQ scores between the two cohorts. However, a significant difference (with unequal variances, $P = 0.0009$) in total NEI-VFQ scores was found between the cohorts using similar t-test approach. Univariate, unadjusted two-sample t-tests were applied to the individual NEI-VFQ subscales and showed that the ocular cohort had significantly lower mean scores in 7 of the 12 NEI-VFQ subscales: general vision ($P = 0.008$), near vision ($P = 0.04$), peripheral vision ($P = 0.042$), mental health ($P < 0.001$), social functioning ($P = 0.036$), role difficulties ($P = 0.004$), driving ($P = 0.005$), and dependency ($P = 0.005$) to the non-ocular group.

In the entire cohort, multiple linear regression models showed that annual income of ≤ $50,000 was associated with significantly lower total SHQ scores ($P = 0.008$) while African American participants had higher total SHQ scores compared to other participants ($P = 0.043$) after controlling for other demographic variables. No significant associations were noted for the NEI-VFQ.

When the variable of ocular involvement was added in the multiple linear regression analyses, total NEI-VFQ scores of the ocular group were significantly ($P = 0.002$) lower than the non-ocular group when adjusted for demographic variables. Participants who had ocular disease and were earning an annual household income ≤$50,000 had significantly lower total SHQ scores ($P = 0.007$) while African Americans with ocular disease had higher total SHQ scores ($P = 0.035$). None of the demographic variables or presence of ocular involvement had significant impact on NEI-VFQ scores (Table 2).

In the ocular cohort, univariate, unadjusted ANOVA was applied to determine the impact of ocular factors (visual acuity, laterality of eye involvement, location of uveitis, activity of uveitis) on the total SHQ and NEI-VFQ scores. The test revealed that individuals with visual acuity equal or worse than 20/100 had significantly lower total NEI-VFQ scores ($P = 0.026$). The "best" multiple linear regression models were selected based on the AIC criterion and fitted to determine associations between demographic, clinical, and ophthalmologic factors on the total SHQ and total NEI-VFQ scores of the ocular group showed that participants with ocular sarcoidosis with annual household earning of equal or less than $50,000 had significantly lower total SHQ ($P = 0.004$) and total NEI-VFQ scores ($P = 0.017$) (Table 3).

DISCUSSION

Ocular sarcoidosis affects the physical functioning by compromising both the visual functioning,[24] and physiological status of an individual.[12] Visual impairment is known to be associated with poor HRQOL and increased symptoms of depression and anxiety.[19,20] Individuals with ocular sarcoidosis require frequent medical visits to manage their disease and undergo invasive intraocular procedures which are associated with stress and anxiety.[21] This study shows that ocular involvement in sarcoidosis affects both vision and health related quality of life. This effect appears more pronounced among patients with lower visual acuity, and those with a lower income. While race appeared to be a significant factor for a lower HRQOL in sarcoidosis patients,[25] this association did not persist in this study but it showed that African American participants had higher health related quality compared to participants from other races as affirmed by their significantly higher total SHQ scores ($P = 0.02$) and NEI-VFQ general health scores ($P = 0.05$). This may be related to the oversampling of African Americans (AA) in the study (68.4%) who have less pulmonary but more ocular involvement compared to participants from other racial groups. African American participants also reported lesser ocular pain (AA mean = 76.35, other races mean = 69.80) which may be attributed to a larger number of AA (N = 39/65, 60%) receiving some form of treatment (oral steroid, steroid-sparing agents, or a combination of both) for their sarcoidosis compared to participants from other races (40%, N = 12/30). In this study, the impact of ocular involvement on vision and health related quality of life was compared in individuals with non-ocular and ocular sarcoidosis. While there have been a number of studies investigating quality of life in different ocular disorders, these do not compare the changes in QOL between different ocular conditions but rather each disease group compared to "healthy" controls.[26–30] Future studies should explore differences in quality of life scores between individuals with ocular sarcoidosis and those with other ocular disease.

Previous outcome measures to address early detection of physical and psychological issues related to systemic sarcoidosis are limited due to their focus on the pulmonary

manifestations of the disease as detected in the radiographic evidence, spirometric values, and gas exchange studies.[31–32] These outcome measures are limited and do not have strong associations with long-term outcomes,[33] and failed to account for each individual response to the physiologic effects of the disease[34] and alterations in functions related to involvement of other bodily systems.[23] Previous studies have also showed conflicting results related to demographic and clinical characteristics of individuals with ocular sarcoidosis. One study showed African Americans with ocular sarcoidosis present with more ocular manifestations, [35] more uveitis, and adnexal granuloma than their Caucasian counterparts.[14] Another showed that Caucasians were more likely to present with posterior uveitis and have more ocular morbidity such as cystoid macular edema. [36]

This study showed that visual acuity was the only ocular factor that had an impact on NEI-VFQ scores in the ocular sarcoidosis cohort. Although a previous study showed that uveitis patients with pan or posterior type of uveitis and those with active uveitis had significantly lower total NEI-VFQ scores compared to controls,[17] we were unable to detect any significant associations between NEI-VFQ scores and location and activity of uveitis. Previous outcome measures to address early detection of physical and psychological issues related to systemic sarcoidosis are limited due to their focus on the pulmonary manifestations of the disease as detected in the radiographic evidence, spirometric values, and gas exchange studies. These outcome measures do not have strong associations with long-term outcomes and failed to account for each individual response to the effects of the disease.[23,31–34] This study showed a direct link of the impact of demographic and clinical variables to the total SHQ and NEI-VFQ scores of individuals with ocular sarcoidosis compared to those with pulmonary sarcoidosis.

This study showed that income was significantly associated with lower NEI-VFQ scores in patients with ocular sarcoidosis. Similarly previous studies showed that low income and limited access to health care among sarcoidosis patients were associated with depression,[15] disease severity,[37] and worsening symptoms among pulmonary sarcoidosis patients.[38] One study concluded that patients with pulmonary sarcoidosis who have no health insurance or on Medicaid were more likely to have functional limitations, severe pulmonary symptoms and worsening health status.[39] This study corroborates those findings but this is the first study, to our knowledge that specifically focused on the impact of demographic and clinical factors on the QOL of patients with ocular sarcoidosis.

Driving scores using the NEI-VFQ are expected to be lower among patients with ocular sarcoidosis compared to non-ocular, interestingly, mental health, role difficulty and dependency scores were also unfavorably affected in the ocular group. This could very well be secondary to the chronic relapsing nature of the disease and visual impairment which may lead to unemployment or underemployment. Based on our study findings, it can be inferred that there is an economic impact of this disease that needs further investigation. It might be related to costly treatment options that become even a bigger issue with loss of vision and possibly employment.

The findings of this study can only be generalized to the setting and the specific population studied. Since the study was conducted in a tertiary, highly specialized uveitis service, it is possible that the results of this study may reflect a tertiary care bias and may not be applicable to patients seen in community settings.

The most significant finding of this study is that ocular sarcoidosis is associated with poor patient reported outcomes that appear to be related to both vision and overall health. Clinicians should consider early referral to an ophthalmologist for evaluation and treatment not only to protect visual functioning but to avoid unnecessary medical and economic

burden brought about by the challenging course of the disease. A uveitis specialist should be considered for patients requiring systemic therapy soon after the diagnosis of ocular sarcoidosis. Equally important is the economic impact of the disease which needs a more integrated approach in the management of these individuals so appropriate services and referrals can be provided. Public health measures are necessary to improve the socioeconomic status of these patients (eg, physical and skills rehabilitation programs), as well as improving access to comprehensive primary and ophthalmological care. Studies exploring health care access among individuals with ocular sarcoidosis and the economic burden of the disease might be an important expansion of this study.

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TABLE 1

Demographic and clinical characteristics of sample

	Ocular (n = 60)	Non-ocular (n = 35)	Total (n = 95)
Demographic Characteristics			
Age (in years), mean (range)	47 (22–65)	50 (35–65)	48 (22–65)
Gender, n (%)			
Female	45 (75.0)	27 (77.1)	72 (75.8)
Race, n (%)			
African American	49 (81.7)	16 (45.7)	65 (68.4)
Others	11 (18.3)	19 (54.3)	30 (31.6)
Annual income, n (%)			
≤ $50,000	30 (50.0)	20 (57.1)	50 (52.6)
Consanguinity, n (%)			
Immediate family	2 (3.3)	2 (5.7)	4 (4.2)
Extended family	7 (11.7)	2 (5.7)	9 (9.5)
Environmental exposures, n (%)			
Central Air	41 (68.3)	30 (85.7)	71 (74.7)
Bedding materials	17 (28.3)	16 (45.7)	33 (34.7)
Tuberculosis	9 (15.0)	1 (31.4)	20 (21.1)
Agricultural chemicals	2 (3.3)	2 (5.7)	4 (4.2)
Rock dust	3 (5.0)	3 (8.6)	6 (6.3)
Automobile fluid	1 (1.7)	4 (11.4)	5 (5.3)
Clinical Characteristics			
ACE, n (%) (n_missing=26)			
Above normal	14 (31.8, n = 44)	11 (44.0, n = 25)	25 (36.2, n = 69)
CXR/CT chest, n (%) (n_missing=34)			
Abnormal	30 (78.9, n = 38)	18 (78.3, n = 23)	48 (78.7, n = 61)
DLCO, n (%) (n_missing=62)			
<60% of predicted	4 (16.7, n = 24)	3 (33.3, n = 9)	7 (21.2, n = 33)
Treatment, n (%)			
Treatment	39 (65.0)	12 (34.3)	51 (53.7)
None	21 (35.0)	23 (65.7)	44 (46.3)
Disease duration (in years), mean (range)	10 (0.2–40)	10 (0.5–42)	10 (0.2–42)
Ophthalmologic Manifestations			
Visual Acuity, n (%)			
20/100 or worse	11 (18)		
Laterality, n (%)			
Bilateral	49 (82)		
Location, n (%)			
Anterior	10 (17)		

	Ocular (n = 60)	Non-ocular (n = 35)	Total (n = 95)
Demographic Characteristics			
Intermediate	25 (42)		
Posterior	8 (13)		
Panuveitis	17 (28)		
Ocular Inflammation, n (%)			
Active	21 (35)		

ACE, Angiotensin Converting Enzyme; CXR/CT, Chest X-ray/Computed Tomography; DLCO, Diffusion Lung Capacity for Carbon Monoxide.

TABLE 2

Multiple linear regression of NEI-VFQ and SHQ scores in the entire cohort

	SHQ Total Score			NEI-VFQ Total Score		
	mean	**coefficient**	***P* value**	**mean**	**coefficient**	***P* value**
Sarcoidosis						
Ocular	3.88	−0.13	0.52	69.08	−13.64	0.00†
Non-ocular	4.01	ref	82.72	ref		
Age	48.28	−0.01	0.16	48.28	−0.09	0.66
Income						
<50K	3.71	−0.49	0.01†	74.15	−3.51	0.37
>50K	4.19	ref		77.66	ref	
Gender						
Female	4.04	0.18	0.38	77.00	2.20	0.62
Male	3.86	ref		74.80	ref	
Race						
AA	4.18	0.45	0.035*	77.75	3.70	0.43
Others	3.72	ref		74.05	ref	
Disease duration	10.21	−0.0030	0.75	10.21	−0.12	0.55
Treatment						
Treatment	4.02	0.15	0.44	75.72	−0.36	0.93
None	3.88	ref		76.08	ref	

*$p < 0.05$,

†$p \leq 0.01$.

AA, African American; NEI, National Eye Institute; VFQ, Visual Functioning Questionnaire.

TABLE 3

Multiple linear regression in ocular cohort based on AIC criterion

	SHQ total score		
	mean	**coefficient**	***P* value**
Age	47.28	−0.02	0.10
Income			
≤50K	3.79	−0.63	0.00†
>50K	4.42	ref	
Disease duration	10.28	−0.01	0.22
Visual acuity			
20/100 or worse	4.13	0.05	0.86
Better than 20/100	4.08	ref	
Laterality			
Bilateral	3.99	−0.22	0.46
Unilateral	4.22	ref	
Location			
Anterior	4.09	−0.08	0.46
Intermediate	3.86	−0.32	
Panuveitis	4.28	0.10	
Posterior	4.18	ref	
Ocular inflammation			
Active	4.18	0.15	0.52
Inactive	4.03	ref	
	NEI-VFQ total score		
	mean	coefficient	*P* value
Age	47.28	−0.24	0.33
Income			
≤50K	61.98	−8.45	0.11
>50K	70.43	ref	
Treatment			
Treatment	63.31	−5.80	0.32
None	69.10	ref	
Visual acuity			
20/100 or worse	58.46	−15.49	0.03*
Better than 20/100	73.95	ref	
Location			
Anterior	71.65	8.12	0.58
Intermediate	68.75	5.22	
Panuveitis	60.90	−2.63	
Posterior	63.53	ref	

	SHQ total score		
	mean	**coefficient**	***P* value**
Ocular inflammation			
Active	65.90	−0.62	0.91
Inactive	66.51	ref	

*$P < 0.05$,

†$P \leq 0.01$.

AIC, Akaike's Information Criterion; SHQ, Sarcoidosis Health Questionnaire