



QUALITY OF LIFE IN SARCOIDOSIS: COMPARING THE IMPACT OF OCULAR AND NON-OCULAR INVOLVEMENT OF THE DISEASE



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Purposes

- 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.

Background

- Sarcoidosis is a chronic, progressive, multisystemic condition of unknown etiology (Curtis, 2001; Spruit, et al., 2005).
- Ocular sarcoidosis can present in 20%–30% of cases and may be the initial manifestation of systemic disease (Bonfioli, 2005; Rothova, 2000).
- Current therapy include immunosuppressive agents that alter disease course and improve health outcomes but carry significant side effects (Judson, et al., 2006; Milman, et al., 2006).

Sarcoidosis and HRQOL

- Mortality rate is low, but the chronic nature can be disabling physically and mentally, especially to those with extrapulmonary involvement (De Vries, et al., 2007; Gvozdenovic, et al., 2008).
- Sarcoidosis patients have lower health-related quality of life compared to healthy controls and even individuals with chronic conditions such as rheumatoid arthritis (Chang, et al., 2001; Wirnsberger, et al., 1999).

Significance of the Study

- Information on quality of life among individuals with ocular sarcoidosis is sparse.
- This study will assess the vision and HRQOL and their relation to specific sociodemographic and clinical features among individuals with ocular and non-ocular sarcoidosis.

Ethical Considerations

- 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 DHHS policy for protection of human research subjects.

Study Design

- This is a cross-sectional study of patients with sarcoidosis with and without ocular involvement.
- Conducted under a prospective, observational research protocol (06-EI-0239, NCT00379275).

Eligibility Criteria

- Inclusion Criteria:
 - clinical diagnosis of sarcoidosis based on radiographic, hematologic, and ophthalmologic findings with or without a supporting histopathologic diagnosis.
 - 18 to 65 years old,
 - able to understand the English language, and
 - able to provide informed consent.

Eligibility Criteria

- Exclusion Criteria:
 - recipients of organ transplantations or has active cancer.
 - has cognitive deficits that prevented them from completing the questionnaires.

Note: For participants with severe visual impairment, a study coordinator was available to administer the questionnaires.

Methods

- Participants were seen from August 31, 2006 until November 15, 2007 at NEI outpatient clinic.
- Three forms to complete:
 - The vision-related quality of life questionnaire, National Eye Institute Visual Function Questionnaire (NEI-VFQ),
 - The HRQOL questionnaire, Sarcoidosis Health Questionnaire (SHQ),
 - Demographic/environmental exposure survey.

Instruments

- NEI-VFQ has 25-items to assess 12 QOL subscales:
general health, general vision, near vision, distance vision, driving, peripheral vision, color vision, ocular pain, role difficulties, dependency, social functioning, and mental health (20-30 min).
- SHQ has 29-items, designed to measure three domains:
daily functioning, physical functioning, and emotional functioning (10-20 min).

Instruments

- Demographic/environmental exposure survey
- Additional data from review of medical records.

Study Procedures

- Diagnostic exams:
 - pulmonary function testing,
 - high resolution chest CT/chest X-ray,
 - 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.

Study Procedures

- Both SHQ and NEI-VFQ were administered by NIH-credentialed clinicians with experience administering forms.
- All study participants completed both questionnaires upon arrival to the clinic prior to their ophthalmic examinations to avoid extraneous influences on their responses.

Participants

- Participants grouped into two cohorts: ocular and non-ocular.
- Ocular group: with uveitis, optic neuritis, and sclerokeratitis with or without systemic involvement. Patients further categorized depending on location of uveitis: anterior, intermediate, posterior, panuveitis
- Non-ocular group: systemic involvement with no ocular disease at baseline.

Statistical Analyses

- Descriptive statistics for the demographic and clinical characteristics.
- Univariate, two-sample *t*-tests to compare means of QOL scores between the two cohorts.
- Multiple linear regression to determine association between demographic/clinical characteristics and QOL scores.
- All data analyzed using Statistical Analysis System, version 11.

Results

110 Individuals approached

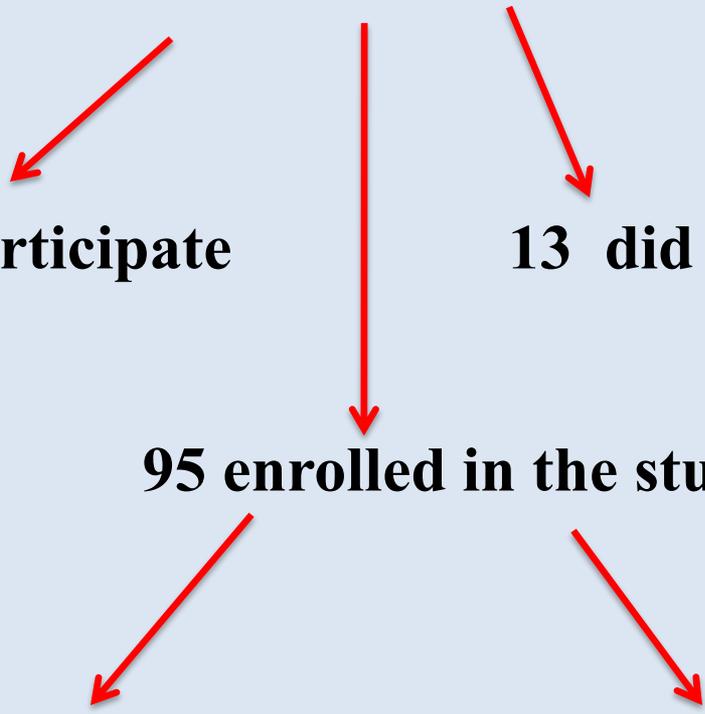
2 refused to participate

13 did not meet inclusion criteria

95 enrolled in the study

60 Ocular group

35 Non-ocular group



Demographic Characteristics

	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

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)		
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.

Results

- 80% (N=76/95) were diagnosed by tissue biopsy and 20% had clinical diagnosis.
- Two sample t-test:
 1. SHQ - no significant difference between cohorts
 2. NEI-VFQ – ocular cohort had lower
 - i. General vision ($p=0.008$)
 - ii. Near vision ($p=0.04$)
 - ii. Peripheral vision ($p=0.04$)
 - iii. Mental health ($p<0.001$)
 - iv. Social functioning ($p=0.04$)
 - v. Role difficulties ($p=0.004$)
 - vi. Driving ($p=0.005$)
 - vii. Dependency ($p=0.005$).....compared to the non-ocular group.

Results

TABLE 2 Multiple linear regression of NEI-VFQ and SHQ scores in the entire cohort

	SHQ Total Score			NEI-VFQ Total Score		
	mean	coefficient	<i>P</i> value	mean	coefficient	<i>P</i> 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.

Results

TABLE 3 Multiple linear regression in ocular cohort based on AIC criterion

	SHQ total score				NEI-VFQ total score		
	mean	coefficient	<i>P</i> value		mean	coefficient	<i>P</i> value
Age	47.28	-0.02	0.10	Age	47.28	-0.24	0.33
Income				Income			
≤50K	3.79	-0.63	0.00†	≤50K	61.98	-8.45	0.11
>50K	4.42	ref		>50K	70.43	ref	
Disease duration	10.28	-0.01	0.22	Treatment			
Visual acuity				Treatment	63.31	-5.80	0.32
20/100 or worse	4.13	0.05	0.86	None	69.10	ref	
Better than 20/100	4.08	ref		Visual acuity			
Laterality				20/100 or worse	58.46	-15.49	0.03*
Bilateral	3.99	-0.22	0.46	Better than 20/100	73.95	ref	
Unilateral	4.22	ref		Location			
Location				Anterior	71.65	8.12	0.58
Anterior	4.09	-0.08	0.46	Intermediate	68.75	5.22	
Intermediate	3.86	-0.32		Panuveitis	60.90	-2.63	
Panuveitis	4.28	0.10		Posterior	63.53	ref	
Posterior	4.18	ref		Ocular inflammation			
Ocular inflammation				Active	65.90	-0.62	0.91
Active	4.18	0.15	0.52	Inactive	66.51	ref	
Inactive	4.03	ref					

* $P < 0.05$, † $P < 0.01$.

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

Results

- Driving, mental health, role performance, and sense of dependency were unfavorably affected in the ocular group according to NEI-VFQ scores.
- African Americans had higher SHQ ($p=0.03$)
- Visual acuity was the only ocular factor affecting NEI-VFQ scores in the ocular cohort.
- Lower income associated with lower SHQ scores.

Summary of Results

- Ocular sarcoidosis affects both vision and HRQOL, more pronounced in patients with lower visual acuity and lower income.
- African Americans had higher SHQ.
- Visual acuity was the only ocular factor affecting NEI-VFQ scores in the ocular cohort.
- Lower income associated with lower SHQ.

Limitation

- Tertiary care bias in the results and may not be applied to community settings.

Nursing Implications

- Education: understanding about sarcoidosis
- Practice: recognition of symptoms and counsel to seek early eye exam, comprehensive individualized care plans
- Research: nurse-led educational interventions to improve health outcomes

Conclusions

- Economic impact of the disease requires integrated approach to management.
- Public health measures are required to improve physical and rehabilitative needs as well as health access.
- Economic burden of ocular sarcoidosis would be a great follow-up study.

Collaborators

NEI Collaborators:

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Questions?

Nursing research develops knowledge to:

- Build the scientific foundation for clinical practice
- Prevent disease and disability
- Manage and eliminate symptoms caused by illness
- Enhance end-of-life and palliative care