

OBSERVATIONAL STUDY

Ophthalmologic profile among Hansen's disease patients in a tertiary hospital

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ABSTRACT

Background: Ophthalmologic evaluation is often neglected in routine screening of Hansen's disease patients. In line with the global aim of reducing grade 2 disability, eye examination should be an essential part of routine examination of Hansen's disease patients.

Objective: To describe the ophthalmologic profile of patients with Hansen's disease seen in a tertiary hospital.

Methods: A point-prevalence survey was conducted. Sixty-six Hansen's disease patients, aged 18 and above, underwent complete ophthalmologic examination including visual acuity, refraction, external eye examination, intraocular pressure determination, dilated pupil examination, palpebral aperture measurement, corneal sensation testing, and tear breakup time determination. Statistical analysis was done.

Results: All patients had ocular findings with lepromatous leprosy (62%) being the highest. Fifty-three percent had Type 2 lepra reaction. Most were males, disease duration in majority was < 5 years and bacillary morphologic index was 4.0 – 4.99. Patients with Grade 1 and Grade 2 disability of the eyes were 62% and 17% respectively. The most common ocular complications were: abnormal tear breakup time (79%), cataracts (53%), blepharitis (47%), madarosis (39%) and corneal opacities (24%).

Conclusion: There is a significant number of ocular findings among leprosy patients in this study. The highest number of ocular complications is among patients in the lepromatous pole. There is a preference of M. leprae for cooler areas; hence, the anterior chamber was greatly affected.

Key words: leprosy, Hansen's disease, ophthalmologic examination

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INTRODUCTION

Hansen's Disease, also known as Leprosy, is a chronic granulomatous infectious disease caused by *Mycobacterium leprae*, with its spectrum characterized based on the clinical, bacteriological, immunological and dermatological state.¹ The two suggested route of transmission of this gram positive, obligate, intracellular, acid-fast bacilli is via skin and respiratory tract.² Major organs to be affected by this disease are the skin, peripheral nerves and upper respiratory tract mucosa, although other organs can be involved including the eyes.^{3,4}

Majority of the new cases were from South East Asia Region, which accounted for 71% of those detected worldwide in 2012. The Philippines was among the countries that were reported to have more new cases in 2012 than in the previous year. Over the

last three decades there have been 16 million Hansen's disease patients treated and cured with MDT in 112 countries.⁵ Although considered cured of leprosy after treatment, many of them are still left with the burden of the accompanying physical disabilities.³ As WHO's global leprosy control strategy to reduce the disease burden through early detection and treatment with multidrug therapy and at the same time reach its set goal for 2015 of reducing new cases with visible deformity or grade 2 disabilities per 100,000 people by 35% compared to that of 2010.⁵

Worldwide, a major struggle that is continuously being encountered by leprosy control efforts has always been disabilities associated with Hansen's disease.⁶ It has been noted that of all systemic diseases, Hansen's disease has the highest incidence of ophthalmologic complications.⁷ The mechanism behind ocular involvement in leprosy maybe due to any of the four ways: (i) by direct invasion of the ciliary body by the lepra bacilli via blood stream followed by spread into other eye structures, (ii) by involvement of the 7th cranial nerve or the ophthalmic division of the 5th cranial nerve, (iii) by formation of hypersensitivity reaction to released antigenic substances from breakdown of leprae bacilli, or (iv) resultant changes to skin of the eye, lids and tear drainage system.⁸ Leprosy generally affects extra-ocular and anterior segment structures of the eye. This may be due to the fact it provides a satisfactory environment for *M. leprae*. Though rarely, posterior segment structures of the eye may also be involved.⁹

Factors that are known to influence the incidence of ophthalmologic complications are increasing age, duration of the disease, type of leprosy, type and duration of treatment received, and type of reactions of leprosy.¹⁰⁻¹³

The importance of this study is to inform medical practitioners of the importance of ophthalmologic evaluation as a part of routine screening of patients diagnosed with Hansen's Disease. Monitoring of eye findings among Hansen's disease patients undergoing treatment should not be overlooked since these patients are at high risk of developing ophthalmological complications. This will be an eye-opener to medical practitioners of who among the Hansen's disease patients are predisposed to the development of eye complications; hence, referral to an ophthalmologist can be done for further evaluation and management. Early diagnosis and management of eye complications can lessen grade 2 ocular disabilities among Hansen's disease patients.

MATERIALS AND METHODOLOGY

Study Population

All Hansen's disease patients ages ≥ 18 years old, seen and diagnosed from July to September 2014 at the Dermatology Out Patient Department of a tertiary hospital based on clinical evaluation, slit skin smear, and histopathologic findings.

Study Procedure

Patients were classified according to clinical spectrum and presence or absence of lepra reactions. A detailed past medical history was also obtained from the Hansen's disease patients including duration of the disease, type and duration of treatment, and presence of diabetes and/or hypertension. Past medications given to the patients were also recorded. Fasting blood sugar (FBS) levels was obtained from all participants.

A detailed ocular examination followed and was done by the same ophthalmologist in a tertiary hospital. The following assessment procedures were done on the patients:

1. Manifest and Best Corrected Visual Acuity (BCVA) with pinhole and/or corrective glasses using a Bailey-Lovie eye chart.
2. Testing for pupillary direct and consensual reaction to light including Marcus-Gunn pupil (RAPD).
3. Gross examination of ocular adnexa (e.g., eyebrows and eyelid for madarosis, lagophthalmos)
4. Manual motor testing of facial nerve (e.g., can close eyes tightly against resistance)
5. Sensory testing of trigeminal nerve (e.g., corneal sensation with wisp of cotton)
6. Slit lamp microscope examination of the cornea, iris and pupil, anterior chamber and lens of the eye, anterior vitreous including tear break up time (TBUT).
7. Intraocular pressure measured using Goldmann applanation tonometer.
8. Pupillary dilation using tropicamide + phenylephrine hydrochloride (5mg/5mg per ml) eye drops, 1 drop every 5 minutes for 2 doses to both eyes.

9. Indirect ophthalmoscopy was done to assess the posterior segment (e.g., macular and peripheral retina and its vasculature, sub retina including choroids and RPE, and optic disc)

STUDY VARIABLES AND OUTCOME MEASURES

The main outcome of interest was the presence of ophthalmologic findings. Those with ophthalmologic findings were described by:

1. Age of the patient in years during time of the registration in the study
2. Sex: as All male and females were included
3. Past medical history: presence of diabetes based on participant's history of any intake of maintenance medications and at the same time acquired individual baseline fasting blood sugar.
4. Clinical spectrum of leprosy (using Ridley-Lopling Classification of Leprosy in Table 1), refers to the classification that identifies the five spectrum of leprosy based on the clinical, bacteriological index and histopathological aspects.
5. Duration of the disease is the time from appearance of typical signs and symptoms of Hansen's Disease as observed by the patient (ex. presence of lesions, nodules, hyposthesia, and numbness) up to the time of study.
6. Type and duration of treatment.

Multidrug therapy is defined as treatment regimen given among leprosy patient according to disease spectrum. WHO has designed blister pack medication kits for leprosy which contains medications for 28 days. The blister pack medication kit is further categorized as follows:

a. Paucibacillary therapy

Paucibacillary therapy for adult is Rifampicin 600mg once a month and Dapsone 100mg daily to complete 6 blister packs to be taken within a maximum period of 9 months.

b. Multibacillary therapy

Multibacillary therapy for adult consist of Rifampicin 600mg monthly, Dapsone 100mg daily and Clofazimine 300mg monthly and 50 mg daily to complete 12 blister packs within a maximum of 18 months.

7. Type of lepra reaction according to National Leprosy Eradication Programme (NLEP) Training Manual for medical officers 2013.

8. WHO disability grading of the eyes

STATISTICAL ANALYSIS

All data were recorded using Microsoft Access. Data analysis were done using STATA 11.0. Frequencies and proportions of qualitative variables were used to analyze other data. Mean and standard deviation were used in summarizing quantitative data.

RESULTS

Demographics

A total of 66 patients were included during the study period, 42 (64%) of whom were male and 24 (36%) were female. The patients' age ranged from 19 to 88 years old with a mean of 51 (standard deviation of 15) and a median of 50. Most of the patients were in the age range of 41 to 60 years (Table 1).

Table 1. Distribution of patients with Hansen's disease based on age group

Age Range	Total
18-40 years	14 (21%)
41-60 years	34 (52%)
≥ 61 years	18 (27.27%)

Clinical Spectrum

The tables below describe the distribution of all patients included in the study classified as to clinical spectrum of leprosy. Lepromatous leprosy

was the most common spectrum (Table 2). Majority of the patients had the disease for less than 5 years (Table 3). Most patients had a bacillary morphologic index of 4.00 – 4.99 (Table 4). Thirty-five patients (53%) manifested Type 2 reaction with no Type 1 reaction observed (Table 5).

Table 2. Distribution of patients with Hansen’s disease based on leprosy spectrum

Leprosy Spectrum	Total
Tuberculoid Leprosy	1 (2%)
Borderline Tuberculoid Leprosy	2 (3%)
Borderline Leprosy	12 (18%)
Borderline Lepromatous	12 (18%)
Lepromatous Leprosy	39 (59%)

Table 3. Distribution of patients with Hansen’s disease by duration of disease

Duration of Disease	Total
< 5 years	29 (44%)
5 – 20 years	11 (17%)
> 20 years	26 (39%)

Table 4. Distribution of patients with Hansen’s disease by Bacillary Morphologic Index

Bacillary Morphologic Index (BMI)	Total
Negative	2 (3%)
0.0 – 0.99	2 (3%)
> 20 years	5 (8%)
2.00 – 2.99	6 (9%)
3.00 – 3.99	19 (29%)
4.00 – 4.99	32 (48%)

Table 5. Distributions of patients with Hansen’s disease by type of leprosy reactions

Reactions	Total
Type 1	0
Type 2	35 (53%)

Drug Therapy and Co-Morbid Conditions

All 66 patients (100%) were on MB multidrug therapy. There were 11 (17%) patients who had concomitant diabetes. Hypertension was noted in 12 (18%) of the patients.

Ophthalmologic Profile

Ocular findings were found in 100% of patients (Table 6).

Table 6. Frequency of ocular findings among patients with Hansen’s Disease.

Leprosy Spectrum	Number of patients with ocular findings
Lepromatous	51 (77%)
Borderline	12 (18%)
Tuberculoid	3 (5%)
Total with ocular findings	66 (100%)

Baseline visual acuity in both eyes was measured followed by determination of the best corrected visual acuity. Most patients had normal best corrected visual acuity in one or both eyes. There were 6 patients who were legally blind (i.e. worse than 6/60) in both eyes (Table 7). WHO disability grading of the eyes were determined (Table 8). The distribution of ocular adnexae pathology was recorded (Table 9).

Table 7. Distribution of patients with Hansen’s disease by visual acuity

Best Corrected Visual Acuity	Number of Patients
Normal in both eyes 6/6	17 (26%)
Normal in one eye, 6/60 or better on the other eye	16 (24%)
Normal in one eye, worse than 6/60 on the other eye	2 (3%)
Both eyes not normal but at least 6/60 or better	22 (33%)
One eye worse than normal but at least 6/60 or better, other eye worse than 6/60	3 (4%)
Both eyes worse than 6/60	6 (9%)

Table 8. Distribution of patients with Hansen’s disease based on WHO Disability Grading of the Eye

WHO Grading	Number of Patients
Grade 0	14 (21%)
Grade 2	41 (62%)
Grade 3	11 (17%)

Table 9. Distribution of patients with Hansen’s Disease based on ocular adnexae pathology

Orbital Adnexae and Lids	Both Eyes	One Eye	Total
Madarosis	24	2	26 (29%)
Lagophthalmos	4	6	10 (15%)
Blepharochalasis	3	0	3 (4%)
Blepharitis	31	0	31 (47%)
Ectropion	1	2	3 (4%)

The anterior segment of the eye is composed of the following structures : iris, cornea, ciliary body and lens. Pigmented keratic precipitates (KP), iris synechiae, and ectropion uvea were observed in the iris and anterior chamber (Table 10).

Table 10. Distribution of patients with Hansen’s Disease based on Iris and Anterior Chamber pathology

Iris and Anterior Chamber	Both Eyes	One Eye	Total
Pigmented KPs	1	2	3 (4%)
Ectropion Uvea	1	1	2 (3%)
Synechiae	1	6	7 (11%)

Corneal opacities (scars, punctate or band keratopathy and pannus) were observed in 16 (24%) patients (Table 11).

Table 11. Distribution of patients with Hansen’s Disease based on corneal opacity

Corneal Opacity	Both Eyes	One Eye	Total
Corneal Opacities (scars, punctate or band keratopathy and pannus)	8	8	16 (24%)

Cataract in either one or both eyes was noted in 35 (53%) patients. Pseudophakia was seen in 6 (9%) patients while aphakia was observed in 3 (4%) patients. The lens can not be assessed in 4 patients due to media opacity. Clear lens was apparent in the remaining 25 (38%) patients (Table 12).

Table 12. Distribution of patients with Hansen’s Disease based on lens findings

Lens	Both Eyes	One Eye	Total
Cataract	32	3	35 (53%)
Pseudophakia	1	5	6 (9%)
Aphakia	0	3	3 (4%)
Not Assessed	1	3	4 (6%)
Clear lens	25	0	25 (38%)

Dilated pupil examination revealed tessellated fundus appearance in 47 (71%) of patients. In 41 (62%) patients, retinal pigment epithelial changes were observed in one or both eyes (Table 13). The tear breakup time was abnormal in both eyes in 76% of patients (Table 14). The distribution of ocular findings per clinical spectrum was determined (Table 15).

Table 13. Distribution of patients with Hansen’s disease posterior segment changes

Posterior Segment	Both Eyes	One Eye	Total
Tessellated Fundus	41	6	47 (71%)
Retinal Pigment Epithelial Changes	31	10	41 (62%)
Can not view	2	4	6 (9%)

Table 14. Distribution of patients with Hansen’s disease posterior segment changes

Tear Breakup Time	Both Eyes	One Eye
Normal (≥ 10 sec)	14 (21%)	2 (3%)
Abnormal (< 10 sec)	50 (76%)	2 (3%)

Table 15. Distribution of ocular complications per clinical spectrum

Ocular Complications	Lepromatous/ Borderline Lepromatous (n=51)	Borderline (n=12)	Tuberculoid / Borderline Tuberculoid (n=3)
Madarosis	23 (45%)	3 (25%)	0
Lagophthalmos	10 (20%)	0	0
Blepharochalasis	2 (4%)	0	1 (33%)
Blepharitis	26 (51%)	3 (25%)	2 (67%)
Ectropion	3 (6%)	0	0
Corneal Opacity	10 (20%)	5 (42%)	1 (33%)
Abnormal TBUT	39 (75%)	11 (92%)	2 (67%)
Cataracts	30 (59%)	2 (17%)	3 (100%)

DISCUSSION

In this study, Hansen’s disease was most common among the age groups of 41-60 years old (52%) with male preponderance (64%) similar to the study done by Wani et. al.⁹

The distribution of patients according to clinical spectrum of patients included in the study are as follows: tuberculoid (5%), borderline (18%), and lepromatous (77%). With regards to duration of the disease, forty-two percent of patients had leprosy for less than 5 years, 18% from 5 to 20 years, and 39% for more than 20 years.

Except for the 3% who had a negative bacillary morphologic index, the rest were positive for slit skin smear with 48% having a BMI of 4.00-4.99.

Fifty-three percent of the patients had Type 2 lepra reaction and none have Type 1 lepra reaction.

All patients were on multidrug therapy.

The ophthalmic manifestations reported can not be exclusively attributed to Hansen’s disease. Among the patients with cataract, the contributory role of a concomitant systemic illness like diabetes can not be totally ruled out especially in the younger age group.

Although hypertension was reported in 18% of the patients, none of the retinal findings reported can be attributed to it.

Disability grading for the eyes was based on best corrected visual acuity.¹⁵ Based on the WHO disability grading, 62% of patients had grade 1 and 17% of patients had grade 2 disability. Only 21% had Grade 0 disability. Six of these patients were classified as legally blind in one or both eyes. This underscores the need for a comprehensive eye examination and timely intervention that could have prevented or at least mitigated undesirable visual outcomes and the resulting disability.

Most common ocular adnexal findings reported in this study were blepharitis (Fig. 1) and madarosis (Fig. 2). The incidence of madarosis due to leprosy varies in various studies and it has been reported to be present in up to 45-76% of the multibacillary leprosy cases in some studies. Madarosis can result from bacillary infiltration of the tarsus, hair follicles and other adnexal structures.¹⁶ Chronic blepharitis is the most common condition associated with madarosis.¹⁷ Blepharitis could either be the cause or sequelae of madarosis but it can not be solely attributed to leprosy.

The pigmented KPs and synechiae might be suggestive of previous unabated uveitic (iritocyclitis or panuveitis) episodes. Iritocyclitis is common in lepromatous leprosy and in many Asian countries. It is the most common cause of blindness in Hansen's patients.¹⁸

Dense corneal opacities (Fig. 3) were seen in 24% of patients and this can cause severe visual impairment. These opacities may have resulted from trauma and/or subsequent corneal ulcer formation. Impaired corneal sensation in the affected eye of leprosy patients can be one of the reasons for breakdown of the ulcer through indiscriminate rubbing of the eye due to insensitivity.¹⁹

The most common lens finding was cataract of varying degree in more than half of the patients. However, this finding may not be specific to leprosy since factors like age, intake of corticosteroids and presence of co-morbidities may have contributed to its development.

Ocular complications were mostly seen in the anterior chamber, iris, cornea, ciliary body and lens. This is because the anterior segment provides a favorable environment for *M. leprae* bacilli. Since there are more numerous *M. leprae* in the lepromatous pole, ocular complications becomes more common for this clinical spectrum.¹⁴

The paucity of posterior segment findings among patients in this study is consistent with the natural history of the disease as regards to the preference for areas with cooler temperature, the posterior segment not being one. Moreso, the posterior segment is highly vascularized and a metabolically active organ of the body. The most common posterior segment finding in this study was the tessellated appearance of the fundus (Fig. 4). This pattern appears to be at the level of the choroid. This is commonly seen in patients with myopia but in this study, majority of patients with this pattern were hyperopes. It might be attributed to the intake of clofazimine which is known to cause skin discoloration among patients taking the drug. Although a common finding, it has no effect on the visual acuity.

Tear breakup time is abnormal in majority of patients in this study. This can not be attributed largely to lagophthalmos (Fig. 5) and subsequent exposure keratitis. It is thought that the quality of tear film might be altered in these patients by one or more mechanisms.

Ocular findings were observed in all patients in the lepromatous pole, the most common findings being abnormal tear breakup time, cataract, corneal opacities and madarosis. The least number of ocular findings was reported in patients belonging to the tuberculoid pole. This is consistent with the study done by Kusagur S.R. et al wherein ocular complications are more common in lepromatous than tuberculoid pole.¹⁶

CONCLUSION

Ocular findings were found in 100% of patients. The most common ocular findings found among leprosy patients were abnormal tear breakup time, cataract, corneal opacities and madarosis, of which majority of patients belong to the lepromatous spectrum and having Type 2 lepra reactions. There is a preference of *M. leprae* for cooler areas; hence, the anterior chamber was greatly affected. Most were males, disease duration in majority was < 5 years and bacillary morphologic index was 4.0 – 4.99. Patients with Grade 1 and Grade 2 disability of the eyes were 62% and 17% respectively.

Since almost all patients have an abnormal tear break up time regardless of the clinical spectrum, the use of artificial tears is recommended for all patients with Hansen's disease to prevent unwanted ocular complications.

There is a need for a comprehensive ophthalmologic examination for all leprosy patients with the ultimate objective of preventing severe visual impairment. Ophthalmologic examination should be part of routine screening of all leprosy patients and records of patients should contain WHO Disability for the eyes. It will be important for a referral network among health care centers, sanatoria, and tertiary hospitals to address the potential risk of sight-threatening complications of leprosy. In conjunction to this, for the government authorities (National Leprosy Control Program, Department of Health) to provide basic training and screening tools for eye examinations at the primary health care level.

Figure 1. Blepharitis

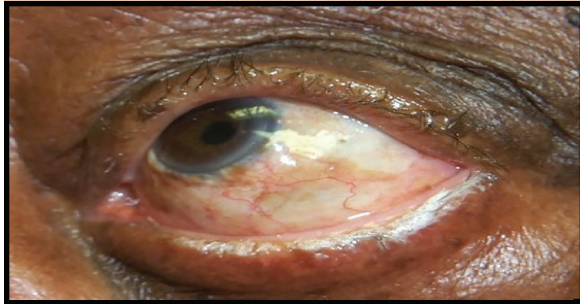


Figure 2. Madarosis



Figure 3. Corneal Opacity

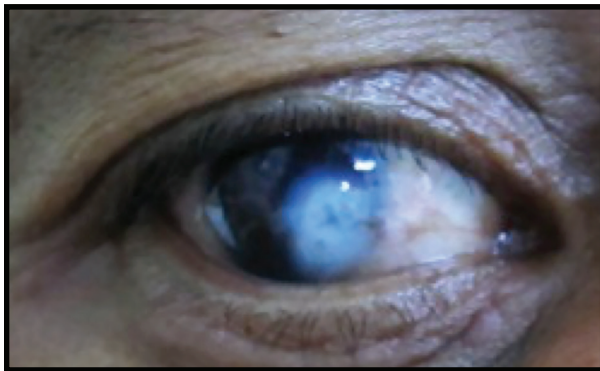


Figure 4. Tessellated Fundus

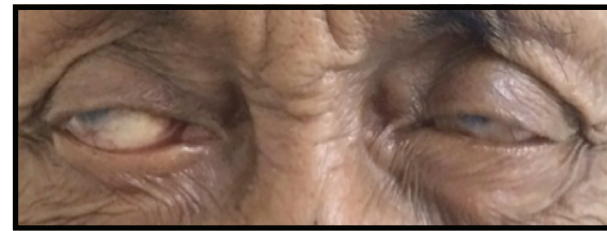
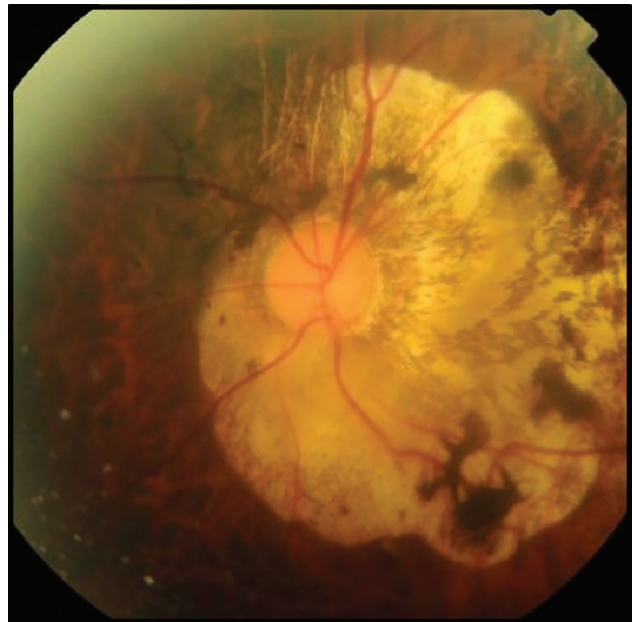


Figure 5. Lagophthalmos

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