Assessment of corneal sensitivity and ocular surface in Hansen's disease patients from a university hospital in Northern Brazil

Avaliação da sensibilidade corneana e da superfície ocular em pacientes com hanseníase de um hospital universitário do Norte do Brasil

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ABSTRACT

Objective: To evaluate changes in corneal sensitivity and ocular surface in leprosy patients from a university hospital in Northern Brazil.

Methods: A case-control study was conducted with 16 leprosy patients (32 eyes) and 20 healthy controls (40 eyes). All participants underwent a single assessment that included ocular surface staining, tear film break-up time test, Schirmer I test, and corneal sensitivity testing using a Semmes-Weinstein aesthesiometer.

Results: Most leprosy patients were male (68.8%), whereas the sex distribution was balanced in the Control Group. The mean age of the leprosy patients was 48.4 ± 19 years, compared to 33.7 ± 14.1 years for the control group. The Schirmer I test showed normal tear production in nearly all eyes (p = 0.061). Tear film instability (tear film break-up time <10 seconds) was observed in 20 eyes, including two cases of severe dry eye. Reduced corneal sensitivity to the blue monofilament was detected in 12.5% of patients with leprosy. Punctate keratitis was present in 81.3% of the leprosy group's eyes, which was significantly different from the control group (p = 0.0266).

Conclusion: Ocular surface alterations were more prevalent among leprosy patients, although not all individual parameters were statistically significant.

RESUMO

Objetivo: Avaliar alterações na sensibilidade corneana e na superfície ocular em pacientes com hanseníase de um hospital universitário do Norte do Brasil.

Métodos: Foi realizado um estudo caso-controle com 16 pacientes com hanseníase (32 olhos) e 20 controles saudáveis (40 olhos). Todos os participantes foram submetidos a uma avaliação única, incluindo coloração da superfície ocular, tempo de ruptura do filme lacrimal, teste de Schirmer I e avaliação da sensibilidade corneana com estesiômetro de Semmes-Weinstein.

Resultados: A maioria dos pacientes com hanseníase era do sexo masculino (68,8%), enquanto a distribuição entre os sexos foi equilibrada no Grupo Controle. A média de idade dos pacientes com hanseníase foi de 48,4 ± 19 anos, comparada a 33,7 ± 14,1 anos nos controles. O teste de Schirmer I demonstrou produção lacrimal normal em quase todos os olhos (p = 0,061). Instabilidade do filme lacrimal (tempo de ruptura do filme lacrimal <10 segundos) foi observada em 20 olhos, incluindo dois classificados como olho seco grave. Redução da sensibilidade corneana ao monofilamento azul foi detectada em 12,5% dos pacientes com hanseníase. Ceratite puntata esteve presente em 81,3% dos olhos do grupo hanseníase, com diferença significativa em comparação aos controles (p = 0,0266).

Conclusão: Alterações da superfície ocular foram mais frequentes entre pacientes com hanseníase, embora nem todos os parâmetros individuais tenham alcançado significância estatística.

INTRODUCTION

Hansen's disease (leprosy) is an infectious-contagious disease caused by the Mycobacterium leprae bacillus, which affects peripheral nerves, from dermal nerve endings to nerve trunks, resulting in deformities and disabilities if not diagnosed and treated early.[1,2] Brazil ranks second in the world and first in the Americas in terms of the number of cases.[3-5]

Ocular tissues can be damaged either directly by the bacillus or indirectly through immunological reactional processes, making ophthalmological alterations more frequent in multibacillary cases compared to paucibacillary cases.[6-8]

Trigeminal nerve damage leads to the development of corneal hypoesthesia, causing harmful consequences to the anterior segment of the eye.[9,10] Corneal lesions are the main cause of blindness among patients with Hansen's disease, despite being a preventable condition.[11-13]

The objective of the present study was to evaluate changes in corneal sensitivity and ocular surface in leprosy patients from a university hospital in Northern Brazil.

METHODS

This is a case-control study conducted in the city of Araguaína, located in the state of Tocantins, in the Northern region of Brazil, from September 2020 to November 2023, approved by the Research Ethics Committee of the *Hospital de Doenças Tropicais* of the *Universidade Federal Tocantins* (UFT) under registration number 15453519.0.0000.8102. The principles described in the Declaration of Helsinki were followed.

Patients diagnosed with leprosy who were treated at the dermatology outpatient clinic of *Hospital de Doenças Tropicais* of UFT were invited to participate in this study and referred to the cornea and ocular surface outpatient clinic at the *Hospital de Olhos Tocantins* (HO Tocantins) for a complete ophthalmological evaluation. The Control Group (CG), consisting of non-leprosy individuals, attended spontaneously by routine appointment at the ophthalmology outpatient clinic of the same hospital.

Patients with other associated chronic infections that could result in peripheral neuropathy, as well as those with chronic alcoholism, diabetes mellitus, hypothyroidism, fibromyalgia syndrome, or those using statins, were excluded from the study.

Informed consent was obtained from 16 leprosy patients (32 eyes) and 20 in the control group (40 eyes) after an explanation of the data collection process and the implications of the study.

All individuals underwent an ophthalmological evaluation of both eyes. The examinations were performed sequentially to minimize environmental interference or reflex lacrimal stimulation caused by the previous test. Initially, the pattern of ocular surface staining and the tear break-up time (TBUT) test were performed, followed by the Schirmer I Test and, finally, the corneal sensitivity test using the Semmes-Weinstein aesthesiometer (SWA).

The evaluation of the anterior segment of the eye was initiated through biomicroscopy examination with a slit lamp (Haag-Streit SLL-3M, Apramed®). After instillation of 1% sodium fluorescein eye drops, the dye impregnation pattern was evaluated using a wide, low-intensity slit lamp beam, and the presence or absence of punctate keratitis was recorded.

The same dye was used in the TBUT test to assess tear film stability. After instilling a drop into the inferior conjunctival sac, the stained tear film on the cornea was observed under cobalt blue light in the slit lamp, and the time until the first tear film break-up was recorded in each eye. A TBUT of less than 10 seconds was considered altered, and a count below 5 seconds was classified as severe dry eye.

To evaluate tear production, the Schirmer I Test (without anesthesia) was applied, using a single-use millimeter-calibrated filter paper strip (Ophthalmos®). The strip was positioned in the temporal portion of the inferior conjunctival sac, removed after five minutes, and the length of the moistened area was measured. A result above 10 mm was considered indicative of dry eye, while values up to 10 mm were considered normal.

The corneal sensitivity test was performed using the SWA, which consists of six rods with monofilaments of nylon of different lengths, diameters, and colors: 0.05 g (green), 0.2 g (blue), 2.0 g (violet), 4.0 g (red), 10.0 g (orange), and 300 g (pink). The evaluation was conducted by touching the instrument to the central cornea, starting with the thinnest and lightest monofilament and progressively moving to thicker and heavier ones, in increasing order, until the patient perceived the stimulus, and the corresponding monofilament color was recorded.

For statistical analysis of possible differences between categorical variables, the Chi-square test and Fisher's exact test were used. A p-value < 0.05 was considered statistically significant.

RESULTS

The study included 20 patients in the CG and 16 patients diagnosed with Hansen's disease (HDG) who were either

undergoing or had completed pharmacological treatment, with 13 of them presenting the multibacillary form. In the HDG, there was a predominance of male patients (68.75%), while in the CG, 50% were female and 50% were male. Mean age was 48.4 ± 19 years (HDG) versus 33.7 ± 14.1 years (CG). Disease duration was < 5 years in 14 patients (87.5%).

Regarding ocular surface parameters, Schirmer I test showed normal tear production in 100% of the eyes in the HDG, while in the CG, 5 eyes presented values below 10 mm (Table 1). However, there was no statistically significant difference between the groups (p = 0.061).

Table 1. Schirmer I Test results in the Hansen's Disease Group and the Control Group

Schirmer Test	HDG	CG	p-value
≥ 10mm	32 (100)	35 (87.5)	
< 10mm	0	5 (12.5)	
Total	32 (100)	40 (100)	0.061

HDG: Hansen's Disease Group; CG: Control Group.
Results expressed as n (%).

Additionally, the instability of the tear film was evaluated using the TBUT test, showing a frequency of 20 of 32 eyes in the HDG with a count of less than 10 seconds, of which 2 eyes were classified as severe dry eyes due to a count of less than 5 seconds. In the CG, most individuals presented a test result of up to 10 seconds (Table 2).

Table 2. Tear film break-up time test results in the Hansen's Disease Group and the Control Group

TBUT, seconds	HDG	CG	p-value
> 10	12 (37.5)	11 (27.5)	
6-10	18 (56.25)	18 (45)	
≤ 5	2 (6.25)	11 (27.5)	
Total	32 (100)	40 (100)	0.069

TBUT: tear break-up time test; HDG: Hansen's Disease Group; CG: Control Group.
Results expressed as n (%).

When evaluating the ocular surface staining with fluorescein, a statistically significant difference was observed between the HDG and the CG (p = 0.0266). There was a prevalence of eyes with punctate keratitis (81.25%) in both eyes of Hansen's disease patients, while in most eyes (55%) of the CG, the ocular surface showed no affinity for the dye (Table 3).

Furthermore, regarding esthesiometry, most individuals from the HDG (87.5% in both eyes) and in the CG (100% in both eyes) showed perceptible sensitivity with the green monofilament. A slight reduction in sensitivity was noted with the blue monofilament in 12.5% of the HDG group. No positive responses were found for the other monofilament colors (Table 4).

Table 3. Ocular surface staining with fluorescein in the Hansen's Disease Group and the Control Group

	HDG	CG	p-value
No alterations	6 (18.75)	22 (55)	
Punctate keratitis	26 (81.25)	18 (45)	
Total	32 (100)	40 (100)	0.0266

HDG: Hansen's Disease Group; CG: Control Group.
Results expressed as n (%).

Table 4. Semmes-Weinstein aesthesiometer test results in the Hansen's Disease Group and the Control Group

SWA	HDG	CG	p-value
Green	28 (87.5)	40 (100)	
Blue	4 (12.5)	0	
Total	32 (100)	40 (100)	0.1905

SWA: Semmes-Weinstein aesthesiometer; HDG: Hansen's Disease Group; CG: Control Group.
Results expressed as n (%).

DISCUSSION

Studies conducted in Brazil and worldwide show that the male-to-female ratio for Hansen's disease is 3:1, which is consistent with the demographic data from this study. This increased proportion remains in multibacillary forms, whereas in paucibacillary cases, there is no significant difference between genders. [14] Some authors justify this by suggesting that, historically, men working outside the home would be more exposed to contagion.[15]

Reduced tear production is reported as one of the complications of Hansen's disease. There is a variation in results among the evaluated studies, such as 62% of low tear production in 150 individuals, 14.2% in 254 patients, and 4.1% in 218 patients, with the latter findings being consistent with the results of this study.[7,16,17]

Although moderate and severe dry eye patterns were observed in the HDG, the high frequency of reduced TBUT in the CG suggests that this finding was not disease specific. Environmental factors, age differences between groups, or unmeasured ocular surface conditions may have contributed to these results. Additionally, the frequency of corneal hypoesthesia in Hansen's disease patients was lower than typically reported in the literature. In contrast, Schirmer I Test, despite the high variability in frequency, showed results similar to other studies.[7,14,16,17]

In this study, 14 participants (87.5%) had been diagnosed with Hansen's disease for less than five years. Reports indicate that ocular alterations appear after 5 to 10 years of disease onset, with a predominance in multibacillary forms, and that these and other factors can determine the frequency and severity of ocular changes in Hansen's disease.[6,9,14] These observations are similar to those of this study, with the multibacillary form being more prevalent among participants. However, the short period since diagnosis in the sample may explain the absence of more severe manifestations in this study.

When evaluating the tear film test with fluorescein, 26 eyes (81.25%) presented punctate keratitis, a higher frequency than observed in other studies, which reported values ranging from 0.7% to 28%.[14,15] Several authors have shown that early nerve involvement reduces trophic support to the corneal epithelium and impairs the blink reflex, both of which are essential for maintaining epithelial integrity.[9] These neurotrophic alterations are known to precede measurable loss of corneal sensitivity because traditional esthesiometry may fail to detect mild dysfunction in the Aδ and C-fiber pathways. As a result, superficial punctate keratitis suggests changes in innervation even in patients with preserved lacrimal function.[8,15-19]

The initial clinical alterations caused by bacillary invasion in the cornea are punctate keratitis lesions, which, if left untreated, can progress to severe corneal damage.[8] Although most patients in the HDG had been diagnosed for less than five years, this finding remains that punctate keratitis may represent one of the earliest ocular indicators of Hansen's disease and warrants closer clinical attention. Furthermore, the clinical appearance of fluorescein staining is characteristic of many ocular diseases and is particularly significant in the detection and monitoring of dry eye, as it indicates compromised cell integrity, such as ruptures in tight junctions of superficial cells or a defective glycocalyx.[16-19]

Additionally, several methods have been developed to evaluate corneal sensitivity, and the Cochet–Bonnet Aesthesiometer (CBA) remains the conventional gold standard in ophthalmology.[20-23] However, its cost, fragility, and limited availability in many clinical and educational settings have motivated the search for alternative tools. In this context, SWA, originally designed for quantitative cutaneous sensitivity testing, has emerged as a practical and accessible option. Its physical characteristics, graded, calibrated monofilaments that deliver standardized bending forces, are physiologically analogous to the pressure-dependent nylon filament used in the CBA, supporting its conceptual equivalence for assessing mechanoreceptor function.[20,21]

This conceptual equivalence has been reinforced by comparative studies showing coherent sensitivity thresholds obtained with both instruments in regions innervated by branches of the trigeminal nerve.[22-25] Santos et al. demonstrated that SWA can discriminate corneal and conjunctival sensitivity in individuals with Hansen's disease, revealing significantly reduced thresholds compared with healthy controls and supporting its capacity to detect disease-related sensory impairment.[11] In addition, a peer-reviewed study directly compared SWA and CBA in the evaluation of corneal sensitivity, concluding that the SWA is a feasible alternative for clinical and research use, particularly in environments where CBA is not readily accessible.[20]

Recent reviews have highlighted the importance of diversifying methods for corneal sensitivity assessment, noting that available tools, including CBA, non-contact esthesiometers, and monofilament-based devices, are complementary and may capture different dimensions of mechanoreceptor function.[26] The present study, together with prior investigations, contributes to expanding the adoption of SWA in ophthalmology, a strategy with meaningful social impact, particularly within educational institutions and public healthcare.[20,22]

Data from previous studies show that corneal sensitivity alterations range from 13.3% to 71.6%.[27-30] The results of this study revealed a lower frequency, likely due to the small sample size, as well as the short disease duration (less than five years) in most participants, which may have contributed to these findings.

Severe ocular alterations are generally present in patients with high bacillary load, late diagnosis, and delayed treatment.[28-30] The study participants came from a reference center for Hansen's disease in Northern Brazil and were therefore well-monitored by a multidisciplinary team for disease management and its possible complications. This may explain the low frequency of ocular alterations observed in the tests performed.

Various ophthalmological alterations, particularly those affecting the ocular surface, can lead to serious consequences such as persistent pain, discomfort, and vision impairment, affecting patients' independence and making daily tasks more difficult.[2,6,9,31] Furthermore, facial deformities and visual impairment can lead to social isolation, depression, and low self-esteem. Early diagnosis strategies and multidisciplinary follow-up through public health policies could help mitigate these impacts.[32-33].

CONCLUSION

Based on these findings, we conclude that a slight reduction in corneal sensitivity was detected in patients with Hansen's disease, whereas ocular surface alterations were more frequent. Although not all parameters reached statistical significance, findings such as reduced TBUT and the high prevalence of punctate keratitis suggest early ocular surface impairment in this population. The ocular manifestations observed appear to be influenced by disease duration and clinical control.

Studies on these ophthalmological findings in the Northern region of Brazil are still scarce. The high prevalence of cases in this region highlights the need for further research on ophthalmological alterations associated with Hansen's disease.

AUTHORS' CONTRIBUTION

J.O. contributed to the conception and design of the study, data acquisition, analysis and interpretation of data, primary drafting of the manuscript, and research group leadership. M.M.S. contributed to the conception and design of the study, data acquisition, and drafting of the manuscript. J.F.A.A. contributed to the drafting of the manuscript. A.C.M.C. and L.F.R contributed to the analysis and interpretation of data. A.C.M.S., J.C.D.A and T.A.A. contributed to the conception and design of the study, analysis and interpretation of data, drafting and critical revision of the manuscript, and administrative, technical, and material support and supervision. All authors critically revised the manuscript and approved the final version of the submitted manuscript.

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