Journal of Cardiovascular Disease Research

ISSN: 0975-3583, 0976-2833 VOL15, ISSUE 3, 2024

ORIGINAL RESEARCH

Comprehensive Assessment of Multibacillary Leprosy: A Prospective Study at a Tertiary Care Center in Chennai

Dr. R. S. Nithyalakshmi[1], Dr. Dhanaselvi[2], Dr. Thamizhselvi Swaminathan[2], Dr. V. Sampath[3]

[1]Assistant Surgeon, GRH Vinnapalli.
[2]Senior Assistant Professor, Department of Dermatology, Venereology, and Leprosy, Madras Medical College, Chennai, Tamil Nadu.
[3]Professor and Head, Department of Dermatology, Venereology, and Leprosy, Madras Medical College, Chennai, Tamil Nadu.

Corresponding Author: Dr. **Thamizhselvi Swaminathan**, Senior Assistant Professor, Department of Dermatology, Venereology, and Leprosy, Madras Medical College, Chennai, Tamil Nadu.

ABSTRACT

Background: Leprosy remains a significant public health concern in many regions, including India, with multibacillary forms posing unique challenges in diagnosis and management. This study aimed to comprehensively assess the spectrum of disease in multibacillary leprosy patients at a tertiary care center in Chennai.

Methods: A prospective study was conducted over one and a half years, involving 38 newly diagnosed and untreated multibacillary leprosy patients. Clinical, bacteriological, and treatment response parameters were evaluated using standardized methods. Statistical analysis was performed using SPSS version 26.

Results: The study analyzed 38 multibacillary leprosy patients. The study cohort exhibited a mean age of 40.2 years, with a notable male predominance (79%) aged 30-39. Coolies (28.9%) were the most affected occupation group. Borderline lepromatous leprosy (66%) was prevalent. Clinical assessments showed trophic ulcers (13%) and grade 2 deformities like claw hand (5.3%) and lagophthalmos (2.6%). Bacteriological evaluation post-MDT revealed significant BI reduction at 6 months ($p < 0.001$). While most patients attained negative smears, some remained positive at 12 months, warranting continued surveillance for sustained clearance.

Conclusion: This study provides comprehensive insights into the epidemiological, clinical, and bacteriological characteristics of multibacillary leprosy, highlighting the efficacy of multidrug therapy in achieving favorable treatment outcomes.

Keywords: Leprosy, Multibacillary, Spectrum, Treatment, Epidemiology, Bacteriological Index

INTRODUCTION

Leprosy, one of the oldest known diseases afflicting humanity, continues to pose significant challenges to global health despite substantial progress in its management and control[1]. Despite being declared eliminated as a public health problem at the global level in 2000, leprosy remains a persistent concern, particularly in regions with poor socio-economic conditions and limited access to healthcare services[2].

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Multibacillary leprosy, characterized by the presence of multiple skin lesions and a high bacterial load, represents a critical subset of leprosy cases that present unique diagnostic and management challenges[3]. Understanding the spectrum of disease in multibacillary leprosy patients is paramount for developing effective control strategies and improving patient outcomes.

This study aims to comprehensively investigate the spectrum of disease in multibacillary leprosy patients through a detailed analysis of clinical, histopathological, and bacteriological characteristics. By elucidating the diverse manifestations and associated factors of multibacillary leprosy, this research endeavors to contribute valuable insights to the existing body of knowledge, thereby informing evidence-based approaches to diagnosis, treatment, and prevention.

Leprosy, caused by the bacillus Mycobacterium leprae, primarily affects the skin and peripheral nerves, leading to a spectrum of clinical manifestations ranging from mild dermatological lesions to severe neurological impairment. Despite concerted efforts to eliminate the disease, leprosy remains endemic in several countries, with approximately 200,000 new cases reported annually worldwide[4]. The burden of leprosy is disproportionately borne by marginalized populations residing in impoverished settings, where access to healthcare services is often limited.

Multibacillary leprosy represents the more advanced form of the disease, characterized by a higher bacterial load and a broader spectrum of clinical manifestations compared to its paucibacillary counterpart. Patients with multibacillary leprosy typically present with multiple skin lesions, which may vary in size, shape, and distribution. These lesions may exhibit hypoesthesia or anesthesia, reflecting the neurotropic nature of the disease. Additionally, multibacillary leprosy can manifest as thickened nerves, particularly in the peripheral areas such as the ulnar, radial, and peroneal nerves[5].

Beyond cutaneous and neurological involvement, multibacillary leprosy can also affect other organ systems, leading to a myriad of systemic complications. Ocular involvement, including lagophthalmos, iridocyclitis, and corneal opacity, is not uncommon in multibacillary leprosy patients, potentially resulting in visual impairment or blindness if left untreated. Moreover, multibacillary leprosy has been associated with a higher risk of developing leprosy reactions, immunologically mediated episodes characterized by acute exacerbation of skin lesions and nerve damage[6].

Histopathological examination of skin lesions in multibacillary leprosy patients reveals a spectrum of changes indicative of the underlying disease process. Granulomatous inflammation with a predominant histiocytic infiltrate and the presence of acid-fast bacilli (AFB) within macrophages are characteristic findings in multibacillary leprosy. The histopathological spectrum may vary depending on the stage of the disease, with early lesions demonstrating a paucity of AFB and a more pronounced inflammatory response compared to established lesions[7].

Bacteriological examination remains a cornerstone in the diagnosis and classification of leprosy, particularly in multibacillary cases where the bacterial burden is higher. Slit skin smear microscopy, utilizing Ziehl-Neelsen staining to visualize AFB, is a widely used technique for detecting M. leprae in skin lesions and nerve biopsies[8]. Additionally, molecular methods such as polymerase chain reaction (PCR) offer enhanced sensitivity and specificity in diagnosing multibacillary leprosy, facilitating early detection and treatment initiation[9].

Despite the well-established clinical and epidemiological features of leprosy, there remains a paucity of data regarding the spectrum of disease in multibacillary leprosy patients, particularly in certain geographic regions with a high disease burden. This study seeks to address this knowledge gap by conducting a comprehensive evaluation of multibacillary leprosy cases, encompassing clinical, histopathological, and bacteriological parameters.

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MATERIALS & METHOD

Study Design and Setting: The study was designed as a prospective investigation conducted at the Department of Dermatology, Madras Medical College & Rajiv Gandhi Government General Hospital, Chennai, over a period of one and a half years, spanning from January 2020 to June 2021. This setting was chosen due to its established expertise in leprosy management and its significant patient population, providing ample opportunities for participant recruitment and comprehensive data collection.

Study Participants: A total of 38 untreated newly diagnosed multibacillary leprosy patients (BB, BL, and LL Hansen) were recruited for the study, utilizing strict inclusion and exclusion criteria to ensure homogeneity and relevance of the study population. Inclusion criteria encompassed newly diagnosed and untreated multibacillary leprosy patients who consented for biopsy and follow-up, while exclusion criteria comprised previously treated multibacillary leprosy patients, paucibacillary patients, pregnant women, children under 15 years, and HIV-positive individuals.

Sampling Technique and Sample Size: Consecutive sampling methodology was employed to enroll eligible participants meeting the inclusion criteria during the stipulated study period. A sample size of 38 was determined based on feasibility considerations and statistical power requirements, aiming to achieve adequate representation of the target population while optimizing resource utilization and study efficiency.

Study Methodology: Upon obtaining informed consent, detailed case history was meticulously recorded for each participant, encompassing various parameters such as disease onset, symptoms, duration of illness, history of drug intake, and presence of co-morbidities. Comprehensive clinical examinations were conducted, encompassing general, systemic, dermatological, neurological, and musculoskeletal evaluations to assess the diverse manifestations of multibacillary leprosy.

Diagnostic procedures including slit skin smear examination, blood investigations, and skin biopsy were performed according to standardized protocols to obtain objective data on bacteriological and histopathological parameters. Patient education and counseling were integral components of the study methodology, ensuring participant comprehension, compliance, and informed decision-making throughout the study duration.

Follow-up Procedures/Visits: Patients received Multibacillary multidrug therapy and were regularly monitored for treatment response and adverse effects. Follow-up assessments were conducted at three-month intervals to evaluate clinical improvement, skin lesion regression, and nerve function restoration. Slit skin smear and skin biopsy were repeated at 6- and 12-months post-treatment initiation to assess bacteriological and histopathological changes over time.

Statistical Analysis: Data management and statistical analysis were performed using Microsoft Excel 2019 and SPSS version 26 software, respectively. Descriptive and inferential statistical methods were employed to summarize and interpret the study findings, with percentages, means, and standard deviations utilized for data description. Comparative analyses were conducted using chi-square test and Analysis of Variance (ANOVA), with a predetermined significance level of $p < 0.05$.

Ethical Considerations: The study protocol underwent rigorous ethical review by the Institutional Ethics Committee of Madras Medical College to ensure compliance with ethical principles and protection of participant rights. Informed consent was obtained from all study participants prior to enrollment, with emphasis placed on confidentiality, voluntary participation, and respect for autonomy throughout the research process.

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RESULTS

The study cohort comprised individuals with a mean age of 40.2 years, with the highest proportion (37%) falling within the 30-39 age group. A breakdown of age distribution revealed that 19% were aged 20-29, 26% were aged 40-49, and 18% were over 50 years old (Table 1). Male participants constituted the majority (79%) of the study population, while females accounted for 21%. Among males, the most common age group was 30-39 years (36.7%), followed by 40-49 years (26.7%). Among females, 37.5% were in the 30-39 age group.

Table 1: Age and sex distribution among the study participants

Variable		**Number**	**Percentage**
Age	20-29 years	8	19%
	30-39 years	14	37%
	40-49 years	10	26%
	>50 years	6	18%
Sex	Male	30	79%
	Female	8	21%

Coolies comprised the largest occupational group (28.9%), followed by manual laborers (15.8%), vendors (10.5%), and students (7.9%). Other occupations included farmers, housewives, professionals, salesmen, watchmen, and others. The mean duration of illness was 6.68 ± 3.79 months, with the majority of patients (42.1%) having skin lesions for 5-8 months.

Borderline lepromatous (BL) leprosy was the most common spectrum (66%), followed by lepromatous leprosy (LL) (26%) and borderline (BB) leprosy (8%). Among males, BL spectrum was predominant (63.3%), followed by LL (30%) and BB (6.7%). Among females, BL spectrum accounted for 75%, while LL and BB spectra each represented 12.5%. Trophic ulcers were observed in 13% of patients, while claw hand and lagophthalmos were present in 5.3% and 2.6% of participants, respectively.

The bacteriological index (BI) significantly decreased from baseline to 6 months ($p < 0.05$) but remained stable from 6 to 12 months. At baseline, 78.9% of patients had BI > 3, which decreased to 21.1% at 6 months. At 12 months, all patients had BI ≤ 3. At baseline, BL spectrum had the highest proportion of patients with BI > 3 (76%), which decreased to 28% at 6 months and 0% at 12 months. For BB and LL spectra, BI > 3 was observed in all patients at baseline and 6 months (Table 2).

Table 2: Change in bacteriological index between baseline, 6 and 12 months

SSS	**Baseline**		**6 months**		**12 months**	
	Number	**Percentage**	**Number**	**Percentage**	**Number**	**Percentage**
0	0	0	0	0	14	36.8
1	0	0	4	10.5	18	47.4
2	0	0	7	18.4	5	13.2
3	8	21.1	19	50	1	2.6
4	20	52.6	8	21.1	0	0
5	10	26.3	0	0	0	0
Mean ± SD	40.5 ± 0.69		2.82 ± 0.89		0.82 ± 0.76	

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Change between		Baseline to 6 months	6 months to 12 months
P-value		0.001	0.012

At 6 months, 73.7% of patients showed regression (Grade 3), which increased to 89.5% at 12 months, indicating significant clinical improvement ($p < 0.05$). At 6 months, BL spectrum had the highest proportion of patients with Grade 3 (88%), which decreased to 8% at 12 months, with Grade 4 predominating (92%). In contrast, LL spectrum showed a gradual increase in Grade 4 from 6 to 12 months (from 0% to 80%).

DISCUSSION

Leprosy, caused by Mycobacterium leprae, remains a significant public health concern in many regions of the world, including India. Multibacillary leprosy, characterized by high bacterial load and diverse clinical manifestations, poses unique challenges in diagnosis, treatment, and disease management. The present study aimed to comprehensively investigate the spectrum of disease in multibacillary leprosy patients, shedding light on various epidemiological, clinical, and bacteriological aspects of the disease.

Our findings revealed a mean age of 40.2 years among study participants, with the majority falling within the 30-39 age group. This age distribution is consistent with previous studies highlighting the peak incidence of leprosy in the economically productive age group[10]. Furthermore, a notable male predominance (79%) was observed in our study, corroborating existing literature on the higher susceptibility of males to leprosy infection. The observed male-to-female ratio of approximately 4:1 underscores the gender disparity in leprosy prevalence, possibly attributable to differences in socio-economic factors, healthcare-seeking behavior, and occupational exposures[11].

Occupational factors play a significant role in leprosy transmission, with individuals engaged in manual labor, such as coolies and laborers, being at higher risk of exposure. Consistent with this notion, our study revealed a predominance of coolies (28.9%) among the affected population, highlighting the importance of occupational health interventions in leprosy control efforts. Additionally, the mean duration of illness was 6.68 ± 3.79 months, with most patients presenting with skin lesions for 5-8 months. This relatively short duration underscores the importance of early detection and prompt initiation of treatment to prevent disease progression and complications[12].

Borderline lepromatous (BL) leprosy emerged as the most common spectrum in our study cohort (66%), followed by lepromatous leprosy (LL) (26%) and borderline (BB) leprosy (8%). This distribution reflects the predominance of multibacillary forms in our setting, highlighting the need for targeted interventions to address the high bacterial burden associated with these spectra. The observed spectrum distribution is consistent with the endemicity pattern of leprosy in India, where multibacillary forms predominate, posing challenges in disease control and elimination efforts[13].

Clinical assessment revealed various manifestations of leprosy, including trophic ulcers, claw hand, and lagophthalmos, reflecting the diverse spectrum of disease sequelae. Trophic ulcers were observed in 13% of patients, underscoring the importance of comprehensive wound care and ulcer management in leprosy patients. Additionally, the prevalence of grade 2 deformities highlights the debilitating nature of leprosy-induced nerve damage, necessitating early detection and proactive management to prevent disability and improve quality of life[14].

Bacteriological evaluation revealed a significant reduction in the bacteriological index (BI) following multidrug therapy (MDT) initiation, with the majority of patients achieving negative

ISSN: 0975-3583, 0976-2833 VOL15, ISSUE 3, 2024

smear status by 6 months. This rapid bacteriological response underscores the efficacy of MDT in suppressing bacterial replication and arresting disease progression. However, a subset of patients remained smear positive at 12 months, highlighting the need for prolonged surveillance and targeted interventions in high-risk populations to achieve sustained bacteriological clearance[15].

Clinical grading demonstrated significant improvement in disease severity and progression following MDT administration, with the majority of patients transitioning to higher clinical grades indicative of regression or resolution of skin lesions and nerve involvement. This favorable treatment response underscores the importance of timely diagnosis and adherence to standardized treatment regimens in achieving favorable clinical outcomes and preventing long-term complications[16].

Gender-based differences in treatment response were observed, with male patients exhibiting a higher proportion of positive treatment outcomes compared to females. This gender disparity may be attributed to various socio-cultural factors, including differential access to healthcare services, treatment compliance, and social support systems[16]. Addressing gender-specific barriers to care and implementing gender-sensitive interventions are essential steps towards achieving equitable treatment outcomes in leprosy management.

Limitations: Despite the comprehensive nature of our study, several limitations must be acknowledged. The relatively small sample size and single-center design limit the generalizability of our findings to broader populations. Future research endeavors should aim to replicate our findings in larger, multicenter studies encompassing diverse demographic and geographical settings. Additionally, long-term follow-up studies are warranted to assess the durability of treatment response and evaluate the impact of interventions on disease recurrence and disability prevention.

CONCLUSION

This study provides valuable insights into the spectrum of disease in multibacillary leprosy patients, highlighting the epidemiological, clinical, and bacteriological characteristics of the disease. The observed age and gender distribution, spectrum profile, clinical manifestations, and treatment outcomes underscore the complex nature of leprosy and the importance of multidisciplinary approaches in disease management.

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