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Original Research Article

Diagnostic limitations in leprosy elimination: A descriptive cross-sectional study from a tertiary care teaching hospital of Kolkata, India

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Abstract

Background: Leprosy is caused by *Mycobacterium leprae*, a weakly acid-fast obligate intracellular bacillus which exhibits tropism for epidermal phagocytes and Schwann cells in peripheral nerves. The incidence and prevalence of leprosy cases have decreased both in India and world-wide since the advent of Multi-drug therapy. The global plan for leprosy eradication includes early detection and treatment of leprosy cases so as to lessen stigma associated with leprosy.
Aim and Objectives: This study aims to assess the clinico-demographic profile of leprosy cases attending a tertiary care teaching hospital of Kolkata, India.
Materials and Methods: We included 112 slit skin smear positive leprosy cases and studied their clinico-demographic profile.
Result and Analysis: Out of 383 suspected cases attending the Department of Dermatology, 329 patients were sent for slit skin smear examination, of which 112 were found to be smear positive. All cases (100%) were multi-bacillary leprosy, 76% were in the age group 21-50 yrs, 22% in the age group above 50 yrs and 2% below 20 years. There was male preponderance (2.1:1). The leprosy cases mosly were resident of Murshidabad (22%) and North-24-Parganas (20%) districts of West Bengal.
Conclusion: The study highlights that actual number of confirmed leprosy cases are more than diagnosed cases. More sensitive tests are required to detect pauci-bacillary cases. Public awareness and active surveillance are needed to detect both new and contact cases. Social stigma associated with leprosy can be minimized by recruiting more female health care workers.

Keywords: Multi-bacillary leprosy, Pauci-bacillary leprosy, Elimination

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1. Introduction

Leprosy caused by *Mycobacterium leprae*, is a chronic infectious disease affecting skin and peripheral nerves. It is also caused by *M. lepromatosis* (a recently discovered species). It is a weakly acid-fast obligate intracellular bacillus belonging to the taxonomic order *Actinomycetales* in the family *Mycobacteriaceae*. Leprosy is a dreaded disease because of the accompanying morbidity and disabilities.[1] *Mycobacterium leprae* causes a persistent granulomatous infection of the skin and peripheral nerves leading to the disease. The cellular immunological response to *Mycobacterium* varies resulting in a clinical spectrum spanning from tuberculoid to lepromatous leprosy. Broad application of multi-drug therapy (MDT) has been linked to a decline in prevalence of leprosy cases. Yet to reduce the incidence globally, leprosy control efforts must be sustained to prevent the disease from spreading that has been there for decades.[2]

Leprosy is diagnosed when at least one of the following cardinal signs is observed:

1. Clear loss of sensation in a pale (hypo-pigmented) or reddish skin patch;
2. Thickened or enlarged peripheral nerve with associated loss of sensation and/or muscle weakness in the area it supplies;

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3. Presence of acid-fast bacilli in a slit-skin smear examination.[3]

A "**new case**" of leprosy refers to a patient diagnosed with the disease who has not previously received treatment. According to the 2009 National Leprosy Eradication Programme (NLEP), pauci-bacillary (PB) and multi-bacillary (MB) cases are defined as follows:

PB cases: Involve up to 5 anaesthetic skin lesions, no nerve involvement or single nerve involvement with or without 1 – 5 skin lesions and negative skin smear at all sites.

MB cases: Involve 6 or more anaesthetic skin lesions, multiple nerve involvement regardless of the number of skin lesions, and a positive skin smear at any site.[3]

Leprosy remains a significant health and economic challenge in developing countries, often concentrated in specific geographic areas or ethnic groups.[4]

Early detection tools for diagnosis of leprosy can drastically impact disease transmission and clinical outcomes by enabling timely treatment for early-stage leprosy.[5]

Though leprosy cases have declined both in India and globally, a major challenge persists in detection of new cases, as reflected by a relatively steady new case detection rate (NCDR) over the past four decades. Despite the nationwide declaration of leprosy eradication in India in January 2006 (prevalence rate below 1 case per 10,000 population), 19% of districts have reported prevalence rate above 1 case per 10,000 population.[6,7]

According to the World Health Organization (WHO), eradication of a disease implies no new case being detected, whereas elimination of a disease is denoted by less than 1 case per 10,000 population. During 2022, globally 1,74,087 new cases were reported amounting to a detection rate of 21.8 per million population, representing an increase of 23.8% compared to 1,40,594 new cases in 2021. According to the National Leprosy Eradication Programme (NLEP), the incidence of leprosy cases decreased to 0.67 per 10,000 population in 2018. Total 60% of all newly reported cases globally are from India. In 2021–2022, there were 75,394 new cases of leprosy recorded annually in India, accounting for 53.6% of all new cases globally.[8] Since the introduction of multi-drug therapy (MDT), there has been a notable decline in both the incidence and prevalence of leprosy cases. Early detection and the continuation of active surveillance were given priority in the worldwide leprosy eradication strategies from 2006 to 2015. The degree to which disease load has decreased was measured by the presence of grade-2 disability (G2D) or visible abnormalities in new cases. Since 2016, reducing the stigma associated with leprosy patients have been one of the strategies of leprosy eradication.[8]

2. Aims and Objectives

The study aims to assess the clinico-demographic profile of leprosy cases at a tertiary care teaching hospital of Kolkata, India.

3. Materials and Methods

A descriptive cross-sectional study was conducted in the Department of Microbiology, NRSMC&H on suspected leprosy cases with reference to their clinico-demographic profile.

3.1. Inclusion criteria

All suspected leprosy patients including newly diagnosed cases and cases already on MDT for evaluation attending Dermatology OPD and admitted in the in-patient ward who were sent to the Department of Microbiology, NRSMC&H for diagnosis and have given written informed consent were included in the study.

3.2. Exclusion criteria

Patients not suspected of leprosy or not given informed written consent were excluded from the study.

3.3. Study period

The study was conducted from January 2022 to December 2023 on suspected leprosy cases from the Department of Dermatology, who were sent to the Department of Microbiology, NRSMC&H for slit-skin smear examination.

3.4. Study design

Slit-skin smear samples were collected from suspected leprosy cases and were examined using modified Ziehl Neelsen (ZN) staining. Follow-up patients were evaluated on the basis of their slit-skin smear to see the progression of disease and correlation with Bacteriological index (BI) and Morphological index (MI) at regular intervals.

Sample size calculation

Sample size was calculated using a formula based on cross-sectional survey:

$[n=Z^2PQ/E^2]$, where Z=1.96(two tailed) at 95% confidence interval

P = Proportion of leprosy cases as reported in previous study

Q = Complement of P i.e. (100-P)

E = Allowable error around the reported proportion which will be considered 7 (absolute for the current study)

Considering P to be 18.5%,[21] the sample size for the study will be:

n = (3.84 × 18. 5× 81.5)/49 =118

[Proportion of Leprosy cases in previous study by Sharma M *et al.* was found to be 18.5%].[21]

Sampling will be done on the basis of proportional to population size (PPS).

4. Result

This study included 383 clinically diagnosed leprosy cases attending the Department of Dermatology, during the period of January 2022 to December 2023. Of which 62% (n=237) were MB cases and rest were PB cases (n=146) (38%) **(Figure 1).** Male: Female ratio was 2.1:1.

Of the 329 patients, who were sent for slit skin smear examination to the Department of Microbiology, 112 were found to be smear positive **(Figure 6)**. All 112 smear positive cases were MB (multi-bacillary) leprosy.

Out of these 112 MB cases, the maximum were in the age group 21-50 yrs(76%), followed by 22% who were above 50 years and only 2% were below 20 yrs **(Figure 3).** The male: female ratio was 2.1:1(males-76, females-36) in the study **(Figure 2)**.

Demographic distribution as shown in **(Figure 4)**, out of smear-positive cases 22% resided in Murshidabad, 20% from North 24 Parganas and Nadia, 18% from Kolkata, 7% from Hooghly and Bankura followed by 4%, and 2% from Howrah and Purba-Barddhaman districts.

Out of 112 cases, there were 14 defaulters, 4 developed deformities,**(Figure 5)** 7 had complications in the form of Type 2 *lepra* reaction, 14 lost to follow-up, 5 had a relapse of the disease and were restarted on MDT. In these 2 years of the study period, 22 new cases were detected by slit skin smear.

Figure 1 shows the total number of MB and PB leprosy cases attending the Department of Dermatology during the study period was 383, among them 38% (n=146) were PB cases and the rest 62% (n= 237) were MB cases.

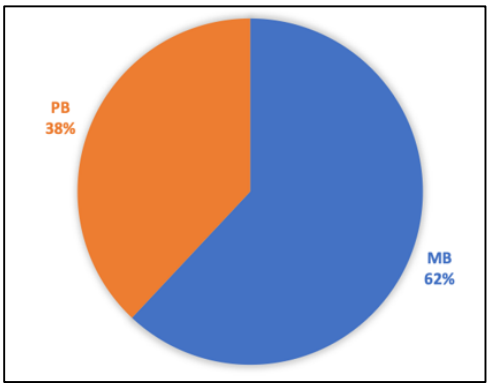

Figure 1: Graphical representation of pauci-bacillary and multi-bacillary cases (%) from January'2022 to December' 2023

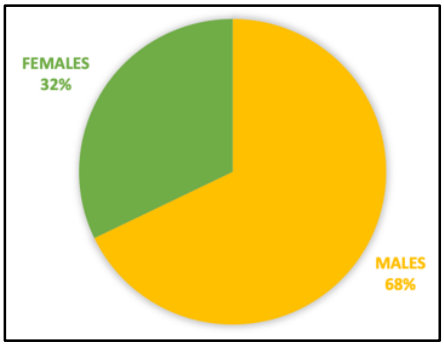

Figure 2: Gender wise distribution among 112 smear positive cases during the time period January 2022 to December 2023

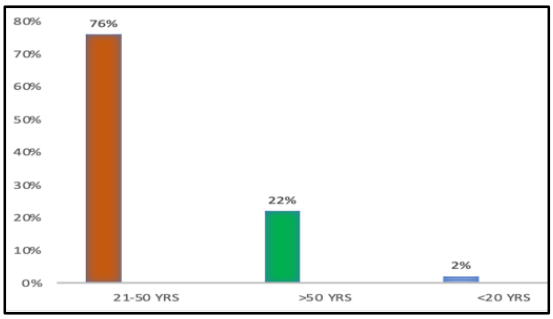

Figure 3: Age wise distribution among 112 smear positive cases during the time period January 2022 to December 2023

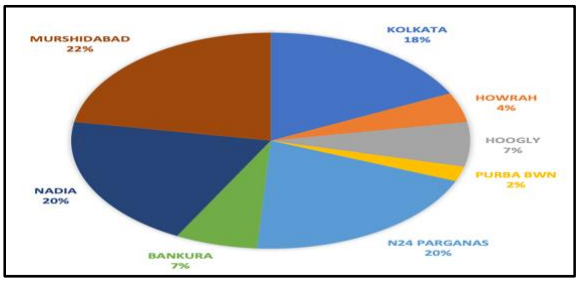

Figure 4: Demographic distribution among slit skin positive patients during the time period of January 2022 and December 2023

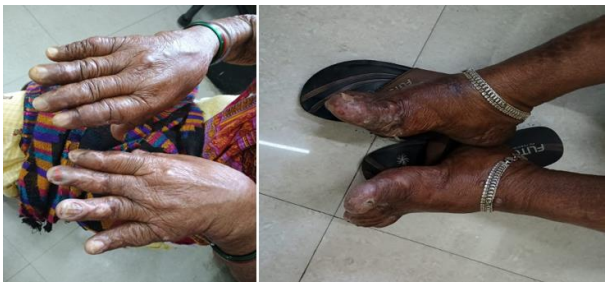

Figure 5: Images of patients suffering from lepromatous leprosy, who have visited our hospital and are on medication.

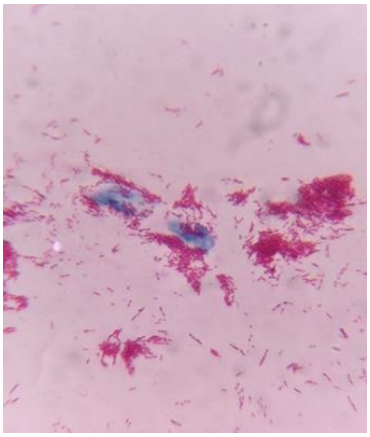

Figure 6: Slit skin smear examination of a patient with globi.

5. Discussion

Our data indicate that males were more commonly affected than females, a finding consistent with previous studies conducted by Ramos *et al.* and de Oliveira *et al*.[9,10] In agreement with these results, Barua *et al.* reported a male-to-female ratio of 2.3:1, supporting the results observed in our study.[11]

The higher incidence of leprosy among male patients compared to female patients may be attributed to the social stigma faced by females, along with the fear of social isolation, which could discourage them from seeking medical attention. However, this gender disparity could be mitigated through the implementation of several targeted measures:

1. Enhancing Early Diagnosis and Care: Improving access to early diagnosis and treatment for women, alongside efforts to increase their awareness and education about the importance of seeking medical care for any skin-related conditions, may reduce the gender gap in case detection.
2. Addressing Pregnancy-Related Risks: Rather than solely providing general advice, women should be specifically informed about the potential risks of pregnancy associated with leprosy, as well as the adverse effects of related medications, to facilitate informed decision-making.
3. Support Systems for Treatment Adherence: The use of calendars or support from family members can be encouraged to help patients track their treatment regimens, ensuring better adherence and reducing the likelihood of treatment interruption.
4. Increasing Female Workforce in Leprosy Care: Hiring more female healthcare workers, particularly in the field of leprosy care, could improve female patients' comfort and willingness to seek and adhere to treatment, fostering a more inclusive and supportive care environment.

By implementing these measures, it may be possible to reduce the social and systemic barriers that contribute to the under-reporting and under-treatment of female leprosy patients.[12]

Analysis of the population data in our study revealed that 76% of cases were in the age group of 21-50 years, representing the middle-aged population, while 22% were aged above 50 years. Only 2% of the cases were observed in the paediatric age group. These findings are consistent with the study conducted by Xiang Li *et al*., who reported 11% cases in children and 89% in adults.[13] Furthermore, our analysis indicates that the age-wise prevalence of leprosy does not show any significant variation, a trend also observed in the available literature across India. However, a noticeable disparity exists among different age groups, suggesting that other factors may contribute to the varying incidence rates across the age spectrum.

Upon examining the district-wise case load of leprosy among patients attending our tertiary care hospital, the majority of cases were reported from Murshidabad (22%), Nadia (20%), and North-24-Parganas (20%). This distribution contrasts with the overall prevalence rate in West Bengal, which stands at 0.5 per 1,000 population, as reported in the National Strategic Plan & Roadmap for Leprosy (2023-2027).[14] However, as our institution serves as a tertiary referral centre for leprosy, patients from all regions of Bengal do not present uniformly, leading to a higher concentration of cases from specific districts.

An interesting observation in our study was the predominance of Multi-bacillary (MB) cases over Pauci-bacillary (PB) cases, in alignment with the updated diagnostic guidelines. According to the new criteria, all smear-positive cases are classified as MB, while PB diagnosis primarily rely on clinical features, as slit-skin smears are unable to detect acid-fast bacilli (AFB) in cases with bacillary concentrations below 10^4 bacilli/ml. This shift towards MB cases is consistent with findings from across the globe. A study by Butlin *et al.* noted a similar rise in MB cases and suggested that this shift is likely influenced by several factors, including modifications in case definitions and potential misclassification by field workers.[15] These findings underscore the evolving landscape of leprosy diagnosis and the need for continuous refinement of diagnostic criteria to accurately reflect the disease burden.

5.1. Early and active detection of leprosy cases

Early and active detection remains a crucial strategy in the fight to eliminate leprosy. Identifying new cases promptly and initiating appropriate treatment regimens is essential to prevent further transmission and minimize the risk of disability. However, several setbacks have hindered progress in this regard.

Under the National Health Mission (NHM) framework, the National Leprosy Eradication Programme (NLEP) initiated targeted case identification efforts in high-

prevalence blocks between 2015 and 2019. These initiatives aimed at early detection and minimizing disability through focused screening and intervention. Unfortunately, the program was abruptly discontinued in 2020, limiting its reach and effectiveness.[16] Additionally, the outbreak of the COVID-19 pandemic further exacerbated the situation, as it diverted attention and resources away from leprosy control programs, focusing primarily on managing the pandemic.[16] The disruption caused by the pandemic significantly hindered ongoing efforts to detect and treat new leprosy cases, leading to potential delays in diagnosis and treatment.

To achieve the goal of a "Leprosy-Free India," it is imperative to reinstate and strengthen early detection programs, ensuring continuous surveillance and timely intervention, particularly in high-prevalence areas. Such efforts must be resilient to external disruptions, such as pandemics, to maintain momentum toward eliminating the disease.

5.2. Breach in transmission

Social and household contacts of individuals with leprosy are at a significantly higher risk of contracting the disease, with studies indicating that they are approximately 3.5 times more likely to develop leprosy than the general population.[17] This increased risk underscores the importance of addressing the transmission dynamics within communities, particularly among close contacts.

To mitigate transmission, the Indian Council of Medical Research (ICMR) launched a Leprosy Case Detection Campaign (LCDC) from 2018 to 2020, targeting 163 districts. This initiative focused on early case detection, followed by the administration of a single dose of rifampicin as chemoprophylaxis to contacts of diagnosed leprosy patients.[17] While this strategy has been approved by both the Government of India and ICMR as a preventive measure, its implementation has faced challenges. The approach remains in its nascent stages, requiring further development and wider adoption to achieve its full potential. Successful nationwide implementation will necessitate greater coordination among various stakeholders, including government agencies, healthcare providers, and non-governmental organizations (NGOs).

To effectively address the breach in transmission and move toward a "Leprosy-Free India", it is crucial to scale up preventive measures, enhance public awareness, and integrate comprehensive community-based strategies to ensure timely and widespread prophylaxis for high-risk groups.

5.3. Availability of diagnostic tests for leprosy

Leprosy diagnosis predominantly relies on two main techniques: (1) clinical features, (2) acid-fast bacilli (AFB) detection via slit skin smear, and (3) skin biopsy. However, these methods have several limitations that impact their diagnostic accuracy and accessibility.

The slit skin smear, commonly used for detecting AFB, is only effective when the bacillary count exceeds 10^4 bacilli/ml. This threshold presents a challenge in identifying cases with lower bacterial loads, such as those with pauci bacillary (PB) leprosy.[7] Furthermore, skin biopsy, while a more definitive diagnostic tool, is not readily available in all healthcare settings due to the need for specialized expertise and proper laboratory infrastructure.

Advances in molecular diagnostics have led to the identification of several *Mycobacterium leprae*-specific antigens, particularly following genome sequencing. Notably, antibodies against phenolic glycolipids-I (PGL-1), a key antigen of *M. leprae*, have been identified. Although PGL-1-based tests have demonstrated high sensitivity in detecting multi-bacillary (MB) cases, they are limited by cross-reactivity with other *Mycobacteria*, such as *Mycobacterium avium* and *Mycobacterium paratuberculosis*, which can reduce the test's specificity.[7]

In recent years, the polymerase chain reaction (PCR) technique has emerged as a promising diagnostic tool for detecting *M. leprae* in clinical specimens. PCR offers a straightforward and accurate method for identifying *M. leprae* DNA or RNA, even in cases with low bacillary loads. Specific genes, such as hsp65, 18kDa, 36kDa, 16SrRNA, sodA, and M. leprae specific repetitive sequences (RLEP), have been utilized to develop M. leprae specific PCR assays. Although PCR has proven successful in research settings and shows potential for clinical use, it is not yet endorsed for widespread use by the National Leprosy Eradication Programme (NLEP) in India.[7]

Additionally, the detection of IgG and IgM antibodies against *M. leprae*, particularly the PGL-1 antibodies, has demonstrated high sensitivity for MB leprosy. However, this test tends to miss PB cases, which are characterised by low bacillary counts and may not trigger a robust antibody response.[18]

Despite these advancements, the primary method for diagnosing leprosy remains a thorough dermato-neurological examination. Given the limitations of current diagnostic tools, particularly in detecting PB cases, there is a pressing need to develop more sensitive and accessible diagnostic methods to ensure timely and accurate diagnosis across all forms of leprosy.

5.4. Therapies in leprosy

The treatment of leprosy has predominantly relied on multi-drug therapy (MDT) since 1982, with the standard regimen consisting of dapsone, clofazimine, and rifampicin. However, the prolonged use of these drugs over several decades raises concerns about the potential development of drug resistance. As resistance to these first-line agents becomes an increasing

possibility, there is an urgent need for the inclusion of second-line drugs in the treatment protocols. Despite this, neither the World Health Organization (WHO) nor the National Leprosy Eradication Programme (NLEP) have yet introduced second-line options.[7]

To address this issue, the incorporation of newer, more potent bactericidal drugs into MDT regimens is crucial. Agents such as clarithromycin, minocycline, ofloxacin, and moxifloxacin, which have shown promising efficacy against *Mycobacterium leprae*, should be considered for inclusion in treatment protocols. These drugs could provide an alternative or supplementary approach to combatting drug-resistant strains of the bacterium.

Furthermore, in countries like the United Kingdom and Japan, the MDT regimen for multi-bacillary (MB) leprosy is often extended for 2-3 years or until the smear becomes negative, demonstrating successful outcomes in reducing relapse rates and improving patient outcomes. Adopting similar strategies in India could help manage more resistant or complicated cases of leprosy, particularly in high-prevalence areas where relapse and resistance are emerging concerns.[19]

To eradicate the disease from India priority should be given to prophylaxis, diagnostic and treatment strategies.[20] Priority areas for which include:

1. Improving and strengthening in health systems at various levels
2. To facilitate access for early detection, appropriate management of cases along with drug resistance of surveillance cases
3. Strategies for prevention
4. Reduction in stigma both in self and community participation
5. Improved management of cases, aftercare and surveillance
6. Environmental factors
7. The use of data management via mobile health(mHealth),electronic health(eHealth) and with the use of artificial intelligence

In summary, while current MDT regimens remain effective, there is a pressing need to evaluate and integrate newer drugs and extend treatment durations in certain cases to ensure the continued effectiveness of leprosy therapies. This will require careful coordination between national health programs, research institutions, and global health organizations to enhance the therapeutic options available for leprosy management.

6. Conclusion

This study underscores several critical points that highlight gaps in current leprosy detection, treatment, and awareness efforts.

6.1. Under diagnosis of leprosy cases

Our findings suggest that we are likely diagnosing only the "tip of the iceberg," with the actual number of cases much higher than reported. Specifically, the current reliance on slit-skin smear examinations may lead to missed diagnosis of pauci bacillary (PB) cases, as the smear test only detects bacillary loads greater than 10^4 bacilli/ml. Therefore, there is a pressing need for more sensitive diagnostic tests to identify PB cases and improve case detection.

6.2. Addressing social stigma and gender barriers

Social stigma surrounding leprosy remains a significant barrier to effective diagnosis and treatment. To combat this, public awareness campaigns must be expanded to reach every corner of society, educating the population about leprosy and dispelling misconceptions. Additionally, there is a need for targeted interventions to raise awareness among women, who may feel uncomfortable seeking care due to stigma. Recruiting more female healthcare workers and attendants in rural and remote areas would provide a more supportive and accessible environment for female patients to openly discuss their symptoms and seek medical help.

6.3. Reinstating active surveillance

Active surveillance, particularly of household and social contacts of leprosy patients, is crucial to preventing further transmission. Such programs, which were disrupted by the COVID-19 pandemic, should be reinvigorated to ensure timely detection of new cases and prompt treatment. Regular monitoring and follow-up for patients already undergoing MDT are also essential to ensure treatment adherence and prevent relapses. The COVID-19 pandemic, which diverted attention and resources, has highlighted the need for robust, ongoing surveillance for all infectious diseases, including leprosy.

6.4. Incorporating molecular diagnostics into NLEP

The use of molecular diagnostic methods, such as PCR, has shown promise in detecting *Mycobacterium leprae* with high sensitivity. While these techniques have been included in the Revised National Tuberculosis Control Program (RNTCP), their integration into the National Leprosy Elimination Program (NLEP) could further enhance case detection and improve diagnostic accuracy. Efforts should be made to incorporate these advanced methods into routine leprosy diagnostics.

6.5. Exploring second-line drug therapies

A critical area for future research involves the incorporation of second-line drugs into the MDT regimen. As drug resistance becomes an increasing concern, particularly for multi-bacillary cases, exploring the use of alternative or supplementary drugs—such as clarithromycin, minocycline, ofloxacin, and moxifloxacin—could help reduce relapse rates

and manage complicated cases. Furthermore, research is needed to assess the impact of these drugs in preventing complications during treatment and improving long-term outcomes for patients.

In conclusion, to move towards the goal of a "Leprosy-Free India", it is essential to address the underreporting of cases, reduce stigma, enhance diagnostic capabilities, and refine treatment strategies. By implementing these measures, improving awareness, and expanding access to better diagnostic and therapeutic options, we can make significant strides in leprosy elimination. Further research and policy reforms are needed to ensure that these challenges are addressed effectively.

7. Limitations of the Study

7.1. Short study duration

The relatively short duration of this study limits our ability to view the current leprosy scenario. A longer study period would have provided a clearer, more detailed picture of the trends in case detection, treatment outcomes, and the evolving epidemiology of leprosy.

7.2. Sample size

The sample size in this study was limited, which may have affected the generalisation of the findings. A larger sample size would have offered a more robust representation of leprosy cases across different districts, providing more reliable insights into regional variations and the broader leprosy burden.

7.3. Geographical scope of the study

As our institute is a tertiary medical college, it primarily serves as a referral centre for complex or advanced cases. This limits the scope of the study to only those patients who sought referral, thus potentially excluding a significant number of milder or early-stage cases. Consequently, the study may not reflect the full spectrum of leprosy cases in the community, especially those in remote or underserved areas.

These limitations highlight the need for future studies with extended durations, larger sample sizes, and more comprehensive geographical coverage to better understand the full scope of leprosy in different regions and to guide more effective intervention strategies.

8. Ethical Clearance

The study protocol was reviewed and approved by the Institutional Ethics Committee (EC/NEW/INST/2023/1862), NRSMC&H.

9. Patient Consent

The authors certify that they have obtained all appropriate consent forms. Patients have agreed for photographs and their consent were taken for clinically relevant pictures to be reported in this journal. Due efforts were made to conceal their identity, but anonymity cannot be granted.

10. Source of Funding

None.

11. Conflicts of Interest

There are no conflicts of interest.

12. Acknowledgments

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