Original Article

Clinicobacteriological Evaluation of Leprosy Patients with 1–5 Skin Lesions

Amir Shahid Ansari, Kshitij Saxena, Kaushal Kumar Singh, Anshul Choudhary, Anukriti Singh, Aditya Kumar Tripathi, Vichitra Sharma

Department of Dermatology, Era's Lucknow Medical College and Hospital, Lucknow Era University, Lucknow, Uttar Pradesh, India

Abstract

Background: *Mycobacterium leprae* is a noncultivable mycobacteria, and diagnosis of the disease is based on its clinical and histopathological characteristics and finding the bacteria in skin scrapings and in biopsies taken from the patients. The aim of this study was to shed light on the clinical classification (based on the number of skin lesions) used extensively in the field where patients classified as paucibacillary (PB) were positive on skin smears and histopathology leading to treatment failure and drug resistance. **Methods:** In this study, we enrolled untreated 62 leprosy patients with 1–5 skin lesions and did a detailed bacterio-histopathological analysis by slit-skin smears (SSSs) and histopathology. **Results:** Of 62 patients analyzed, 15 patients came out to be multibacillary (MB) and 47 were PB by SSS and histopathology. **Conclusion:** The findings of the present study showed that the WHO classification of leprosy based on the number of lesions seems to be inappropriate as it considers a number of MB lesions as PB only, thus misleading the treatment strategies. Hence, it is essential that a comprehensive clinicobacteriological assessment of leprosy cases should be done to ensure the appropriate bacillary status and guiding the appropriate treatment strategy.

Keywords: Bacteriology, histopathology, leprosy, multibacillary, paucibacillary

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Introduction

Leprosy is a chronic granulomatous infection caused by *Mycobacterium leprae* or *Mycobacterium lepromatosis*.[1,2] The National Leprosy Eradication Program under the guidance of the WHO classified leprosy into paucibacillary (PB) and multibacillary (MB) on the basis of the number of skin lesions, nerve involvement, and slit-skin smear (SSS) results.[3] However, SSS is not feasible in the field, resulting in a classification based on the count of skin lesions.[4] Classifying leprosy just by the count of skin lesions is unsatisfactory.[4-6] MB cases labeled as PB in field and subsequently getting PB-multidrug therapy treatment, leads to treatment failure and drug resistance.[7]

Methods

Population

A cross-sectional observational study was done from January 2018 to October 2019 in the Department of Dermatology and Venereology, Era's Lucknow Medical College and Hospital, Lucknow. Untreated Leprosy patients with 1–5 skin lesions, of either gender, were included in the study. Patients with leprosy reactions were excluded from the study.

After enrollment, age, gender, number of lesion, and color of the lesion were noted, and cutaneous examination of lesions was done, and morphology of the lesions, nerve involvement, and deformity were noted. SSS and skin biopsy were performed, and the bacteriological index of smear and bacteriological index of granuloma were assessed on a logarithm scale as defined by Ridley (1958), based on a logarithmic scale and is a modification of Cochrane's index.[3]

Address for correspondence: Dr. Kshitij Saxena, Department of Dermatology Era's Lucknow Medical College and Hospital, Lucknow Era University, Lucknow, Uttar Pradesh, India.
E-mail: drkjsv@gmail.com
ORCID:
https://orcid.org/0000-0002-0946-0121

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Ethical approval

Approval for the conduction of the study was obtained from the institutional ethics committee. Written consent was obtained from all the patients enrolled in the study.

Statistical analysis

The data so collected were fed into the computer using Microsoft Excel 2013. The statistical analysis was performed using the SPSS (Statistical Package for the Social Sciences) Version 21.0 (IBM, Amonk, New York, United states) statistical analysis software for windows. The values were represented in number (%) and mean ± standard deviation.

Results

The present study was carried out to assess the proportion of PB and MB leprosy in leprosy patients with 1–5 skin lesions and to describe their clinicomorphological and bacteriological profiles. A total of 62 patients were enrolled in the study.

Of 62 patients enrolled in the study, a total of 50 (80.6%) were male and 12 (19.4%) were female. The sex ratio (M: F) was 4.17. The age of patients ranged from 5 to 65 years. A maximum number of patients were aged 21–30 years (29%), followed by 11–20 years (27.4%) and 31–40 years (19.4%). A total of 14 (23.3%) patients were >40 years of age. Only 1 (1.6%) patient each was aged <10 years and >60 years, respectively. The mean age of patients was 30.81 ± 14.44 years. The mean age of male patients was 30.66 ± 13.84 years, whereas the mean age of females was 31.42 ± 17.40 years. On evaluating the data statistically, there was no significant difference between the two genders ($P = 0.872$) [Table 1].

Table 1: Association of final diagnosis with different clinicodemographic variables

Characteristic	MB ($n=15$), n (%)	PB ($n=47$), n (%)
Mean age±SD	35.00±16.01	29.47±13.82
Sex		
Male	11 (73.3	39 (83.0
Female	4 (26.7	8 (17.0
Mean number of lesions±SD	2.47±1.19	2.13±1.44
Morphological type		
Macule	7 (46.7)	31 (66.0)
Plaque	8 (53.3)	15 (31.9)
Mixed	0 (0)	1 (2.1)
Nerve involvement	14 (93.3)	42 (89.4)
Deformity	0 (0)	5 (10.6)
SSS		
0	10 (66.7)	47 (100)
3+	3 (20.0)	0 (0)
4+	1 (6.7)	0 (0)
5+	1 (6.7)	0 (0)
HPE		
0	2 (13.3)	47 (100.0)
1+	7 (46.7)	0 (0)
2+	1 (6.7)	0 (0)
3+	3 (20.0)	0 (0)
5+	1 (6.7)	0 (0)
6+	1 (6.7)	0 (0)

PB: Paucibacillary, MB: Multibacillary, SSS: Slit skin smear, SD: Standard deviation, HPE: Histopathologic examination

As per the inclusion criteria, the number of lesions ranged from 1 to 5. The mean number of lesions was 2.21 ± 1.38.

In majority of cases (n = 38; 61.3%), the morphology was macular. A total of 23 (37.1%) had plaque. In remaining 1 (1.6%) case, the morphology was mixed.

A total of 56 (90.3%) cases had nerve involvement, whereas 5 (8.1%) had deformity.

On SSS, most of the samples (91.9%) were scored as 0. A total of 3 (4.8%) were scored as 3+ and 1 (1.6%); each was scored as 4+ and 5+, respectively.

Histopathologically, a total of 49 (79%) were scored as 0, followed by 7 (11.3%) patients who were scored as 1+, 3 (4.8%) scored as 3+, and 1 (1.6%) each scored as 2+, 5+, and 6+, respectively.

According to the final diagnosis, a total of 15 (24.2%) were diagnosed with MB, whereas 47 (75.8%) were diagnosed with PB.

Discussion

Leprosy has existed in the Middle East since Christ and in India since times of the Vedas. India shares records having the highest number of new leprosy cases of the world. Leprosy is endemic in certain parts of India and accounts for 63% of the world leprosy population.[1] The high physical, economic, and social burden associated with leprosy warrants early recognition and treatment strategies. On the basis of bacteriological positivity, the disease is divided into PB and MB types. The detection of the disease is based on clinical diagnosis, and the disease is classified on the number of skin lesions, i.e., <5 lesions were classified as PB, whereas >5 skin lesions were classified as MB leprosy.[8] No doubt this classification is simple in guiding the treatment decisions in low-resource settings where laboratory facilities are not available or are ill-equipped. However, over the time, it has been shown that this classification has its own limitations, and often there is disagreement between clinical and histopathological diagnosis.[9]

The treatment strategies for PB and MB types are different. MB leprosy is treated using a more aggressive approach than PB, as it is targeted on higher bacterial indices. The selection of treatment approach is thus dependent on the clinical spectrum and bacteriological positivity.[9]

The present study was carried out to assess the proportion of bacterio-histopathologically confirmed PB and MB leprosy in leprosy patients with 1–5 skin lesions, which were diagnosed as "PB" clinically.

The age of patients ranged from 5 to 65 years. The mean age of patients was 30.81 ± 14.44 years. Majority of patients (n = 47; 75.8%) were aged between 11 and 40 years. The age profile of

patients in different studies shows dominance of individuals in most productive phase of their life with the mean age generally between 30 and 40 years. In the present study, majority of patients were males, and sex ratio was 4.17. A dominance of males has also been reported in different hospital-based studies.[6,10-15]

In the present study, the maximum number of cases had only one lesion (45.2%); however, the mean number of lesions was 2.21 ± 1.18. In the study by Veena *et al.,*[6] majority of patients had only one lesion (61.2%), whereas only 1 (3.2%) had four lesions. Rao *et al*.[4] studied 77 patients with up to 5 skin lesions, majority of which had single lesions.

In our study, SSS was negative in 57 (91.9%) cases. A total of 5 (8.1%) cases were positive, with scores 3+ in three patients, 4+ and 5+ in one case each. On the other hand, histopathology reports a total of 13 (21%) cases to be acid-fast bacilli positive. There were seven cases with score 1+, three cases with score 3+, and one case each with score 2+, 5+, and 6+, respectively. Overall, on clinicobacteriological evaluation, a total of 15 (24.2%) cases were diagnosed as MB and the remaining 47 (75.8%) were diagnosed with PB.

Our findings showed that clinical diagnosis does not hold exactly true on histopathological correlation. The level of agreement between the two was 75.8%, and disagreement between histopathological and clinical diagnosis was 24.2%. A number of studies have addressed the same issue of agreement between clinical and histopathological diagnosis.

Agreement as low as 24% was observed by Rao *et al.*;[16] however, Santos *et al.*[11] observed an agreement of 93.8%. The findings of the present study are close to that of Veena *et al.*[6], which showed an agreement of 76.6%.

In the postelimination era, new interest is seen in leprosy owing to the reemergence of disease in India and the Western world.[17]

The disagreement between clinical and histopathological diagnosis has its own clinical implications. A misclassification of MB to PB could result in undertreatment problem and drug resistance, whereas misclassification of PB to MB could result in overtreatment and adverse effects. Both scenarios have their physical, emotional, and financial implications. In facilities where histopathological infrastructure is available and functional, histopathological correlation must be done invariably in all the cases to rule out the issue of over/under treatment.

Conclusion

Our study showed that the classification of leprosy based only on the number of skin lesions seems to be inappropriate as it considers a number of MB cases as PB cases, thus misleading the treatment strategies. Hence, it is essential that a comprehensive clinicobacteriological assessment of leprosy cases should be done in every case to ensure the appropriate bacillary status, guiding the treatment strategy and preventing undertreatment and drug resistance.

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Conflicts of interest

There are no conflicts of interest.

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