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A Study of Indices in Smear Positive Leprosy in Post-Elimination Era: Experience at a Teaching Tertiary Care Centre

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Abstract

Background: Leprosy is an oldest chronic infectious disease known to mankind that predominantly affects the skin and peripheral nerves. **Objective:** To evaluate the bacteriological and morphological indices in smear positive cases.

Materials and Method: Retrospective observational study was undertaken for one year duration on suspected cases of leprosy. Smears were prepared from one from each of the ear lobes by slit and scrap method and one from the site of lesion. Smears were stained with modified Ziehl-Neelsen stain and bacteriological/morphological indices were calculated. **Results:** Among 345 clinically suspected cases, 160 (46.38%) were multibacillary with male to female ratio 1.9:1 and most of cases from rural area of lower/middle class of third and fourth decade. All the three sites smears were positive in 112 (70%) cases. 66 (41.25%) cases had bacteriological index of 1+ while more than 1000 bacilli, on average, in 1each oil-immersion field (BI 6+) was observed in 1 (0.62%) cases. In 70 (43.75%) cases morphological index was less than 25 while in 14(8.75%) cases it was more than 50. **Conclusion:** Bacteriological and morphological index is one of the most important tools for diagnosis, classification, monitoring of treatment and disease severity.

Keywords: Bacteriological index, leprosy, multibacillary leprosy, morphological index, paucibacillary leprosy, smear-positive cases

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Introduction

Leprosy is an oldest chronic infectious disease known to mankind that predominantly affects skin and peripheral nerves. In previous era, it was common in temperate climate, now it is mainly confined to tropical and subtropical regions. Although, Mycobacterium leprae, causative organism of leprosy was demonstrated by G.H. Hansen in 1873, it is documented that skeletal evidence for existence of leprosy in human is since 2000BC.[1],[2] Leprosy is clinically diagnosed by finding at least one of the following cardinal signs[3]: a) definite loss of sensation in a pale (hypopigmented) or reddish skin patch; b) thickened or enlarged peripheral nerve, with loss of sensation and/or weakness of the muscle supplied by that nerve; c) presence of acid-fast bacilli in a slit-skin smear. It is a highly variable disease, affecting different people in different ways, according to immune response. It is categorized as paucibacillary case (a case of leprosy with 1 to 5 skin lesion, without demonstrated presence of bacilli in a skin smear) and multibacillary case (a case with more than five skin lesions or with nerve involvement or with the demonstrated presence of bacilli in a slit-skin smear, irrespective of the number of skin lesions. Demonstration of acid-fast lepra bacilli in stained smear is an approach to confirm the diagnosis, monitor the disease progress, treatment outcome and also for calculating bacteriological and morphological indices.[4]

Although, India succeeded in achieving elimination of leprosy at state level in 34 states/Union Territories (UTs) out of 36 states/UTs, India continues to have a high share of 58.8% of the world leprosy population which might be due to India being a vast country with wide variation in health status across its states and it indicates that active transmission of infection has remained unchanged. In the year, 2017–18, a total of 126164 new cases of leprosy were detected with annual case detection rate of 9.27/100000 and prevalence rate of 0.67 per 100000 populations.[5] Since transmission of leprosy is from man to man, the only way to achieve elimination is early diagnosis and treatment. The present study was conducted to determine the pattern, prevalence and trends of smear positive of leprosy cases in a tertiary teaching centre.

Materials and Method

This was a retrospective observational study undertaken at one of the largest tertiary care teaching government referral hospital that provides care to underprivileged, socioeconomically deprived population of central India in the department of microbiology from July 2017 to June 2018. All the cases of suspected leprosy (attended OPD or referral), irrespective of their age and sex were included in the study. Smears were prepared from three sites: one from each ear lobe and one from the site of lesion/active disease. Slit and scrape method was used for collecting sample from ear lobules. The smears were stained with modified Ziehl-Neelsen stain and examined under oil immersion to look for both intra and extracellular organism, and bacteriological and morphological index were calculated.

Bacteriological Index (BI)[6]

Bacteriological index denotes the density of leprae bacilli both living (solid staining) and dead (fragmented or granular) in the smear. According to Ridley's logarithmic scale, it ranged from 0 to 6+ and was based on the number of bacilli seen in an average microscopic field of the smear using an oil-immersion objective.

: No bacilli in any of the 100 oil-immersion fields.

1+: 1–10 bacilli, on an average, in 100 oil-immersion fields.

2+: 1–10 bacilli, on an average, in 10 oil-immersion fields.

3+: 1–10 bacilli, on an average, in each oil-immersion field.

4+: 10–100 bacilli, on an average, in each oil-immersion field.

5+: 100–1000 bacilli, on an average, in each oil-immersion field.

6+: more than 1000 bacilli, an on average, in each oil-immersion field.

Morphological Index (MI)[7]

Morphological index is the percentage of solid staining bacilli in a stained smear. Average MI was calculated for the body as the total of the MIs for all sites divided by the number of sites.

The following criteria were used for calling the bacilli solid rods are

a. Uniform staining of the entire organism
b. Parallel sides
c. Rounded ends, and
d. Length 5 times that of the width.

Observations and Results

A total of 345 smears of clinically suspected cases of leprosy were examined. The males were more than double the females. Most of the cases 198 (57.39%) were falling into age group 21–40 years. Majority of (71.01%) cases were from rural area and more than two-third (86.38%) were from lower and middle socioeconomic class. Among smear positive cases, males were almost double the females, and male to female ratio was 1.9:1: Ninety (56.24%) cases belonged to age group 21–40 years and most of them from rural area of lower and middle socioeconomic class [Table 1].

Variables	All cases (n = 345, %)	Smear positive cases (n = 160, %)
Gender		
Male	248 (71.88)	105 (65.63)
Female	97 (28.11)	55 (34.37)
Age group (in years)		
00–10	9 (2.61)	00
11–20	22 (6.38)	11 (6.88)
21–30	68 (19.71)	33 (20.62)
31–40	130 (37.68)	57 (35.62)
41–50	47 (13.62)	27 (16.88)
51–60	32 (9.28)	16 (10)
61–70	26 (7.54)	13 (8.12)
>70	11 (3.18)	3 (1.88)
Residence		
Rural	245 (71.01)	104 (65)
Urban	100 (28.99)	56 (35)
Socioeconomic status		
Lower	213 (61.74)	94 (58.75)
Middle	85 (24.64)	44 (27.5)
Upper	47 (13.62)	22 (13.75)

Table 1 Demographic profile of study population

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In 185(53.62%) cases, bacilli were not demonstrated (Paucibacillary) while 160 (46.38%) cases were multibacillary [Figure 1]. Of the 160 smear positive cases 66 (41.25%) cases had BI 1+, while BI 6+ was observed in 1(0.62%) case [Table 2] and [Table 3]. In 70 (43.75%) cases MI was less than 25. In 59 (36.87%) cases it was 0 while in only 14 (8.75%) cases, it was more than 50. Among the 160 cases of smear positive most of the cases 112(70%) were positive, in three site smear(two ear lobes and one skin site) [Figure 2].

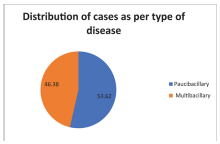

Figure 1 Distribution of Leprosy cases

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Bacteriological Index	Smear positive cases (n=160,%)
1+	66(41.25)
2+	30(18.75)
3+	33(20.63)
4+	20(12.5)
5+	10(6.25)
6+	1(0.62)

Table 2 Bacteriological index among smear positive cases

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Morphological index	Smear positive cases (*n* = 160, %)
>50	14(8.75)
25–50	17(10.63)
<25	70(43.75)
0	59(36.87)

Table 3 Morphological index among smear positive cases

Click here to view

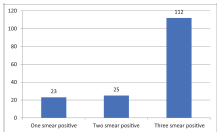

Figure 2 Distribution of smear positive cases according to sites of smear

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Discussion

Although, India is succeeding in achieving elimination of leprosy, it remains an important public health problem in some pockets and clusters. Despite the success of elimination, the fact remains that India continues to account for 60% of new cases reported globally each year and is among the 22 “global priority countries” that contributes 95% of world numbers of leprosy warranting a sustained effort to bring the number down.[8] Both prevalence rate and annual new case detection rate of leprosy was in plateau phase in between 2005–2015 and the latter always exceeded the values of the former. This clearly indicates that although the number of cases as determined by prevalence rate has drastically gone down, a steady level of annual new case detection rate indicates that the active transmission of infection has remained unchanged. Such reports might be because after declaration of elimination of leprosy in 2005; the vertical leprosy control programme was quickly integrated with the general health services.

In present study, males were more than double the females and male to female ratio was 2.6:1. Such a male preponderance might be due to males frequently self-reported for treatment and due to increased mobility and frequent interaction with community leads to an increased opportunity for contacts in males while because of social stigma females are slow to self-report and our observation is supported by various authors.[9],[10],[11],[12] Leprosy was considered to be mostly a rural problem, however, because of the movement of population from rural to urban areas, it is creating problem in the urban areas also.[12] We observed more than two-third of cases were from rural and belonged to lower and middle socioeconomic class which might be due to the fact that our institute provides care to underprivileged, socioeconomically deprived population.

India is a vast country with wide variation in health infrastructure and health status across the various states and India being one of the most endemic countries for leprosy, the proportion of children with the disease assumes more importance, particularly as an indicator for monitoring progress.[13] Infection can take place at any time depending on the opportunities for exposure and in endemic areas, it is commonly acquired during childhood. As leprosy has long incubation period it is commonly found in children of 10–14 years age group, but patients less than one year have been reported by Brubaker *et al*.[14], and the youngest case of leprosy reported in literature is a two and half month old infant whose parents had multibacillary leprosy. More than fifty cases were diagnosed in infancy and various authors speculated on the possibility of vertical/transplacental transmission or through breastfeeding.[15] Similar to Jindal *et al*.[16] and Mathan *et al*.[17] we observed most of the cases 198 (57.39%) were falling into age group 21–40 years and around 9% cases in age group 0–20 years.

Number of skin lesions and/or number of body areas affected is inversely correlated with the protective immunity. According to degree of skin-smear positivity, WHO Study Group on Chemotherapy of Leprosy Control Programme (1981) classified the disease into multibacillary and paucibacillary but later on in sixth meeting of committee (1987), they endorsed that all the patients with smear positive should be classified as multibacillary leprosy. In present study, 185(53.62%) cases were smear negative (paucibacillary) and 160 (46.38%) were smear positive (multibacillary). Our findings are concomitant with the observations of Rao et al[18] and Mahajan *et al*.[19] but other authors reported more of multibacillary cases compared to paucibacillary cases.[11],[12],[20] Among the smear positive cases, in most of the cases112 (70%), all three sites (both ear lobes, active skin lesion site) smear revealed positivity of bacilli indicating high infectivity and low immunity in multibacillary cases.

BI is the only objective way of monitoring the benefit of treatment. This is an expression of the extent of bacterial load in smears (includes both living and dead bacilli). It is important due to its simplicity and is representative of many lesions, but is affected by the depth of the skin incision, the thoroughness of the scrape and the thickness of the film. A more accurate and reliable index of the bacillary content of a lesion is given by the logarithmic index of biopsies (LIB). These indices help to assess the state of patients at the beginning of treatment and to assess the progress.[21] Similar to Kilikdar *et al*. the bacteriological indices of smear positive cases in our study ranged from 1+ to 6+ with majority of cases 66(41.25%) having BI 1+ followed by 3+ BI in 33(20.63%) cases. This 1+ bacteriological index denotes low bacillary load and better prognosis, while high (BI 5+ and 6+) having high bacillary load, highly infectious and are more likely to transmit the disease in community.It is possible to distinguish and count the number of solid staining organisim and irregular staining bacilli on microscopic smear examination and it has been believed that only solid-staining organisms are viable. The percentage of solid staining bacilli in a stained smear is referred to as MI and it is one of the more sensitive parameters of the therapeutic failure, non-compliance, drug resistance or relapse and it has prognostic value.[22] It is also unusual for solid-staining Mycobacterium Leprae to reappear for short periods in patients being successfully treated with drugs. Measurement of MI is liable for observer variations and, therefore, not always reliable and require expert opinion (Microbiologist). We observed in 70(43.75%) smear positive cases, MI was <25, indicating low viable bacilli, low infectivity and better response to treatment.

Although India has announced statistical elimination of leprosy, there are certain challenges. The pockets of high endemicity, hidden cases in community, new case detection rate and disability rate in new cases has been rising. To address there challenges, NLEP advocates a) leprosy case detection campaign in highly endemic district; b) focused leprosy awareness using Accredited Social Health Activist (ASHA) and multipurpose health workers in “Hot Spot “ where new cases with grade 2 disability are detected; and c) area-specific plans for case detection in hard to reach areas. Directorate General of Health Services, Central Leprosy Division, New Delhi has issued guidelines on strengthing of skin smear laboratory for leprosy control activities and programme. However, to ensure uniformity, reliability and high levels of quality and performance, standard continuous monitoring and supervision for the collection and processing of slit-skin smears are necessary.

Conclusion

Leprosy still continues to be a major health challenge and it is more common in lower/ middle socioeconomic class of rural area of third and fourth decade of life. Smear positivity in our study was 46.38% and in most of 70% cases, all three site smears were positive. Among smear positive cases, BI was 1+ in 41.25% and MI was <25 in 43.75%. Slit-skin smear examination is one of the most important tools for diagnosis, classification, monitoring of treatment and disease severity.

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Conflicts of interest

There are no conflicts of interest.

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Figures

[Figure 1], [Figure 2]

Tables

[Table 1], [Table 2], [Table 3]