Clinical study to relook into the case definition and treatment of leprosy

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1. Introduction

Leprosy has been a feared illness since antiquity because of immense stigma associated with it. Unlike tuberculosis, leprosy is not often a direct killer. Instead, due to the predilection of Mycobacterium leprae for skin and peripheral nerves, the serious consequence of leprosy are deformity and disability.1

The introduction of multidrug therapy to leprosy programmes in mid-1980s resulted in a significant reduction in the prevalence of the disease globally.2 The goal of elimination of leprosy as a public health problem as defined by the World Health Assembly i.e, attaining level of prevalence of less than one case per 10,000 population was reached at the global level in the year 2000.3

Though the target of leprosy elimination was achieved at national level in 2005, according to WHO Weekly Epidemiological Record India constitutes 60% of new cases reported globally. The Annual New Case Detection Rate (ANCDR) in India was 9.27 per 100000 population. A total of 1,26,164 new leprosy cases are detected annually (2017-2018) with prevalence rate of 0.67 per 10,000 population in India.4

It is true that a full course of MDT makes leprosy cases non-infectious but it does not prevent occurrence of new cases.5 The statistical elimination of leprosy in India is something to cheer about but the steady appearance of newer cases still haunt us. It is sad to note that countries with high prevalence of Leprosy administer once a month of rifampicin while developed nations administer daily rifampicin.
rifampicin. The present study was performed to analyze the profile of leprosy patients presenting to our tertiary level referral center.

2. Materials and Methods

We have done a retrospective analysis of all the leprosy cases registered from January 2016 to December 2016 in the leprosy clinic of Belagavi Institute of Medical Sciences, India. The data was collated and analyzed according to age, sex, history of household contact, presenting complaint, type of leprosy, slit skin smear report, history of treatment, leprosy reactions, and deformities.

As per WHO classification, the disease was classified as multibacillary (MB) if there were six or more lesions and/or more than one nerve involvement or slit skin smear positive & as paucibacillary (PB) if there were one to five lesions and/or no nerve/only one nerve involvement or negative slit skin smear at all sites.

Patient with clinical signs of leprosy who had not received multi-drug therapy previously was considered as “new case”. Any patient of leprosy who is taking MDT during our study period was considered as “on treatment leprosy case”. Any patient of leprosy who had completed one year of MDT was considered as “treated case of leprosy”.

Cases of lepra reaction are subdivided into type I and type II reaction, depending upon the clinical manifestations. Sudden appearance of erythematous and raised plaques in pre-existing lesions or appearance of new lesions, development of neuritis while under chemotherapy was categorised as type I (reversal) reaction. Development of crops of painful erythematous papules or nodules along with fever and other systemic manifestations was categorised as Erythema nodosum leprosum or type II lepra reaction.

Deformities when present were graded based on WHO grading system. If neither anaesthesia, nor any visible deformity was present, it was called Grade 0. Grade 1 deformity signifies the presence of anaesthesia. Grade 2 signified presence of visible deformities.

3. Results

Out of 64 cases studied, 13 were treated as out-patients and 51 were treated as in-patients and majority were in the age group of 21-40 years (40.6%). Males outnumbered the females with the ratio of 2.2:1. There were 62 (96.9%) cases of multibacillary and only 2(3.1%) cases of paucibacillary. Of total 64 cases, 30 were newly detected, 19 were receiving treatment and 15 cases had completed treatment but had one or more complications. Family history was noted in 4 (6.2%) cases (Table 1).

The most common presenting complaints among total leprosy cases studied were: Multiple painful, reddish raised skin lesions – 24 (37.5%); Spontaneous blisters/Ulcers on the hand/feet – 21(32.8%); Hypopigmented patches – 13 (20.3%). Similarly out of 30 newly diagnosed cases 10 (33.3%) patients presented with multiple reddish raised lesions, 12 (40%) with spontaneous blisters/Ulcers on hand or foot, 10 (33.3%) with Hypopigmented patches (Table 2).

### Table 1: Profile of leprosy patients in the study

| Age            | Number of patients | %     |
|----------------|--------------------|-------|
| <20 years      | 3                  | 4.7%  |
| 21 to 40 years | 26                 | 40.6% |
| 41 to 60 years | 21                 | 32.8% |
| > 60 years     | 14                 | 21.9% |

| Gender         | Number of patients | %     |
|----------------|--------------------|-------|
| Male           |                     |       |
| Female         |                     |       |

| Type of leprosy | Number of patients | %     |
|-----------------|--------------------|-------|
| MB              | 62                 | 96.9% |
| PB              | 2                  | 3.1%  |

| Treatment profile | Number of patients | %     |
|-------------------|--------------------|-------|
| New case          | 30                 | 46.9% |
| On treatment      | 19                 | 29.7% |
| Completed treatment | 15             | 23.4% |

| Family history    | Number of patients | %     |
|-------------------|--------------------|-------|
| Present           | 4                  | 6.2%  |
| Absent            | 60                 | 93.8% |

As per the clinical criteria of WHO, only 37 patients had anaesthetic patches, 52 had nerve thickening and only 11 demonstrated bacilli in the slit skin smear.

Out of total 64 cases 29 (45.3%) patients had lepra reaction of which 14 had type I reaction and 15 had type II reaction. Similarly out of 30 newly diagnosed cases 9 (30%)...
Table 3: Patients satisfying clinical criteria of leprosy according WHO case definition

|                          | Number of total leprosy cases (n=64) | Number of new leprosy cases (n=30) |
|--------------------------|--------------------------------------|-----------------------------------|
| Anaesthetic patches      | 37(57.8%)                            | 18(60%)                           |
| Nerve thickening         | 52(81.3%)                            | 25(83.3%)                         |
| Positive slit skin smear | 18(28.1%)                            | 11(36.7%)                         |

patients had lepra reaction of which 2 had type I and 7 had type II reaction (Figures 1, 2 and 3). Thirty nine (60.9%) out of 64 had deformity; of which 16 patients had grade I deformity and 23 had grade II. Similarly among 30 newly diagnosed cases 17 (56.7%) had deformity; of which 9 had grade I and 8 had grade II deformity (Figures 4 and 5).

4. Discussion

It is essential to have good knowledge and understanding of the epidemiological profile of a disease, to formulate guidelines in its management as a public health problem. In the last 10 years since eradication of leprosy, the scenario has not changed much in terms of the incidence rates.

In our study, majority of patients were in the age group of 21-40 years with males outnumbering females with ratio of 2.2:1, which is similar to the findings reported in many previous studies. This is common pattern in India where males are more vulnerable for acquiring disease because of their lifestyle and socialization. Also they frequently self report for treatment but, females lack health seeking behaviour in accessing the health services.

The percentage of MB cases (96.9%) in our study was significantly higher than PB cases, which is much higher...
than the national average (51.27%). This is similar to other previous studies from India.\(^5_7\) Higher proportion of MB cases in our study indicates delay in detection. 6.2% of the affected patients had a household member also affected with leprosy, which is similar to study by Chhabra et al.\(^7\)

46.9% of our patients were newly diagnosed cases of leprosy which indicates that transmission of leprosy is still continuing in the society and its presentation is changing. Multiple painful reddish raised lesions (37.5%) and ulcers/blisters over the hands/foot (32.8%) along with classical clinical criteria of WHO were seen as the most common presenting complaints among our patients. So there is a delay in the diagnosis of leprosy & indicates a gap between patients and health services. This may be the result of shifting the leprosy work from well trained leprosy workers in the vertical programme to PHC workers who were less trained and skilled in diagnosis of leprosy.

Hence it is essential to relook into case definition as well as complications of leprosy in order to detect the cases early and to rehabilitate the ones who are disabled. Inspite of elimination, the steady appearance of new cases and complications compel us to reconsider the treatment protocol of leprosy followed in our country. For the same hansens disease monthly single dose of Rifampicin is administered in developing countries where as daily dose is followed in developed countries. Hence treatment of each case of leprosy needs to be individualized especially while dealing with cases of high bacillary load.

5. Conclusion
A good number of patients are being seen with lepra reaction or complications. It is quite evident that the presentation of leprosy is changing. This is a paradigm shift in the initial presentation and needs a relook into the existing diagnostic criteria of leprosy.

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7. Conflict of Interest
The authors declare they have no conflict of interest.

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