Study of Clinico-epidemiological Profile and Treatment Outcome of Leprosy Cases as Per Recent National Leprosy Eradication Programme in an Urban Area of Western Maharashtra - A Longitudinal Study

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Leprosy is a chronic infectious disease which affects skin, peripheral nerves, limbs and eyes. National leprosy Eradication Programme (NLEP) gives emphasis on early detection of cases, treatment completion & disability limitation. The newer initiatives are more focused on high prevalent regions while there are few low prevalent regions where prevalence rate is increasing. In view of the recent thrust on leprosy eradication it was felt necessary to study the current profile of leprosy patients including their disabilities & outcome to treatment in a low endemic region. A longitudinal study was carried out in urban leprosy unit and urban health centres of Pune city of Maharashtra. A clinico-epidemiological analysis of all leprosy cases from Oct 2017 to Sep 2018 was done using semi-structured questionnaire and clinical examination. Treatment outcome of all leprosy cases was assessed for entire treatment duration along with evaluation of NLEP using few selected indicators. A total of 89 patients were included in this study who were examined and followed up for treatment duration for clinico-epidemiological profile and treatment outcome. Mean age of study participants is 35.7 years with standard deviation of 15.16. Study showed a very high proportion of multibacillary cases (93.3%). Approximately 27% participants belong to lepromatous leprosy (LL) spectrum while 3.4% to tuberculoid spectrum with rest 70% cases reported as borderline leprosy (BT, BB & BL). In the current study it was observed that 25.8% participants had grade 1 deformity and 11.2% had grade 2 disability (G2D). Majority were released from treatment (88.7%) after completion of MDT while rest could not complete treatment due to various reasons. High percentage of multibacillary cases among new cases and high G2D are indicators of late detection of cases in the community. Few leprosy cases during the study found to have refused treatment. It is recommended that further efforts should be made by the government for raising awareness and empowerment of community so that leprosy cases report early and are treated appropriately.

Keywords: Leprosy, Clinico-epidemiological, NLEP, Maharashtra, Multibacillary, Grade 2 Disability

Introduction

Leprosy affects mainly the skin, peripheral nerves, eyes and mucosa of the upper respiratory tract. If left untreated, leprosy can cause progressive and permanent damage to the skin, nerves, limbs, and eyes (WHO 2018). Leprosy may present with different clinical forms and its diversity is determined by the host immunity towards *Mycobacterium leprae*. Clinically, this disease manifests with localized,

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multiple or disseminated skin patches. Diagnosis is mainly by observing cardinal signs of leprosy i.e., hypopigmented hypo-anaesthetic patches, thickened nerves and presence of acid-fast bacilli in slit skin smear (NLEP 2013). Multidrug therapy using rifampicin, dapsone and clofazimine is the mainstay of leprosy management (WHO 2019). Because of lack of awareness and the stigma & discrimination attached, patients sometimes delay in seeking proper care and treatment until they develop deformities (WHO 2016). Disabilities may occur in various forms, such as limitations of activities involving the use of hands, feet and eyes, as well as restrictions in social participation (Asia et al 2015).

Government of India launched National Leprosy Control Programme in 1955 while National Leprosy Eradication Programme (NLEP) in 1983. India achieved elimination of leprosy in the year 2005 with a prevalence rate of below 1 per 10000 population (Singal & Sonthalia 2013), yet it appears to be far off from achieving eradication. The prevalence rate has come down over the years, however; the percentage of Grade 2 disability amongst new cases detected has increased from 3.10% (2010-11) to 3.61% (2017-18) (NLEP 2019a). So, India is giving emphasis on early detection of cases, treatment completion & disability limitation. Recently few districts which had achieved leprosy elimination earlier have shown higher prevalence and many new are nearing elimination. The focus of the programme is mainly on the high prevalent districts of India while the low prevalent regions historically are less apprehensive of the menace of the disease. In view of the recent thrust on leprosy eradication it was felt necessary to study the current profile of leprosy patients including their disabilities & outcome to treatment in a low endemic region. There is no recent study particularly focusing on change in trends among regions with low endemicity. There is no

exclusive study in the study area chosen for this study which is a predominant urban population. It was felt necessary to study if new programs being launched for early detection of cases in these regions are detecting new cases early and thereby preventing disability.

Patients and Methods

This longitudinal study was carried out at an Urban Leprosy Unit & Urban Health Centres located in Pune city of Western Maharashtra.

Period of study: The study was planned and conceptualized in September-October 2017. Data collection began from October 2017 and continued till September 2019.

Study Population: All newly detected cases of leprosy enlisted at urban leprosy unit for one year from October 2017 to September 2018 were included in the study. Those patients who did not gave consent for the study were excluded.

Sample Size Calculation: Due to low endemicity for leprosy in this urban area of Western Maharashtra (PR - 0.25 to 0.3 per 10,000 population), all cases meeting the inclusion criteria was selected for the study.

Sampling Technique: All consecutive cases within the study period were taken.

Data Collection Tools: Data collection was done using pre-tested interviewer administered questionnaire which included socio-demographic information and information on clinical features & assessment of disability.

All newly detected cases of leprosy enlisted at urban leprosy unit from October 2017 to September 2018 were selected, to allow an observation period of 06 months to 12 months, which is the standard duration of treatment for paucibacillary (PB) and multibacillary (MB) cases respectively. List of cases including addresses & telephone number, was obtained from supervisory urban leprosy unit of the city

every month. All the cases were interviewed and examined by the interviewer at the clinic or at their residence aided by the urban leprosy centre staff. Data was collected by interview technique using a pre-tested structured questionnaire. All cases were followed up monthly telephonically or by interviewing them at urban health centres. Cases were classified into clinical types as per Ridley-Jopling (1966), also classified into PB and MB types for treatment purposes as WHO recommendation followed by NLEP (2013).

Disabilities were graded as per WHO criteria (Brandsma & van Brakel 2003). Investigations & treatment of medical conditions related to leprosy (lepra reactions, adverse drug reactions) and other co-morbidities during the follow up of the study was recorded. Treatment outcome was recorded at the end of observation period by interviewing the patient, clinical examination & medical records at urban leprosy centre. Treatment outcome included adequate treatment, relapsed, defaulter and

Table 1 : Socio-demographic characteristics of study population.

Characteristics		Frequency	Percentage
Age	0-14	06	6.75
	15-29	33	37.1
	30-59	44	49.4
	>60	06	6.75
Gender	Male	60	67.4
	Female	29	32.6
Education	Illiterate	25	28.2
	Primary	23	25.8
	Secondary	13	20.2
	Intermediate	18	14.6
	Graduate & above	10	11.2
Religion	Hindu	75	84.3
	Muslim	13	14.6
	Christian	1	1.1
	Sikh	0	0
Occupation	Unemployed	14	15.7
	Self-employed	25	28.1
	Government	5	5.6
	Private	45	50.6
SES (Kuppuswamy) Inadequate Data (30)	Upper	0	0
	Upper Middle	5	5.6
	Lower Middle	10	11.2
	Upper Lower	22	24.7
	Lower	22	24.7

Table 2 : Clinico-epidemiological profile of study participants.

Characteristics		Frequency	Proportion
Mode of Detection	Self-reported	45	65.2
	Screening	29	17.9
	Referred	27	16.9
Contact History	No	88	98.9
	Yes	01	1.1
Past History of leprosy	No	86	86.6
	Yes	03	3.4
Commonest Presentation	Hypopigmented Patch	70	78.7
	Nerve Involvement	10	11.2
	Deformity	04	4.5
	Plaques/Nodules	04	4.5
	Hyperpigmented Patch	01	1.1
Clinical Type	MB	83	93.3
	PB	06	6.7
Ridley- Jopling Classification	TT	03	3.4
	BT	25	28
	BB	08	9
	BL	29	32.6
	LL	24	27
Grades of Deformity	No Deformity	56	63
	Grade 1	23	25.8
	Grade 2	10	11.2
Nerve Involvement	Single	30	33.7
	Multiple	50	56.1
	No	09	10.1
Commonest Nerve Involvement	Ulnar	64	72
	Lateral Popliteal	43	48
	Median	28	31
	Tibial	25	28
	Radial	20	22
	Greater Auricular Nerve	12	14
Type of Lepra Reaction	No	78	87.6
	Type I	11	12.4
	Type II	0	0
Adverse Drug Reaction	No	80	89.9
	Yes	09	10.1

Sensory Impairment	Yes	67	75.3
	No	22	24.7
Treatment Outcome	Released from Treatment	79	88.7
	Refusal to treatment	03	3.4
	Left area permanently	04	4.5
	Not traceable	03	3.4
	Died	00	0

Table 3 : Indicators for NLEP evaluation.

Indicators	
Annual new case detection rate	2.6 per 1lakh population
Female Rate	32.6%
Child Rate	6.75%
Multibacillary Rate	93.3%
Grade 2 Deformity Rate	11.2%

died. Evaluation of NLEP with respect to certain selected indicators was done using collected data, medical records & inputs from urban leprosy unit key staff interview. Ethical clearance for the study was obtained from the Institutional Ethics Committee and written permission from head of institution and district leprosy office before the start of the study.

Results

A total of 89 patients were included in this study who were examined and followed up for treatment duration for clinico-epidemiological profile and treatment outcome. The socio-demographic characteristics of the study population is summarized in Table 1. Mean age of study participants was 35.7 years with standard deviation of 15.16. The level of education of study participants revealed that more than 50% were educated up to primary level or less. Half of the study participants were privately employed.

The clinic-epidemiological profile of the study population is summarized in Table 2. For majority of participants (65.2%) detection was through self-reporting to urban government designated health centres. Few patients reported history of leprosy in past while one gave history of contact with a leprosy case. Hypopigmented patch was the commonest presentation. Most of the cases belong towards lepromatous end and were multibacillary type. Grade1 disability was observed in 25.8% of patients and Grade2 in 11.2%. Multiple nerve involvement was seen in more than half of study participants with Ulnar nerve the commonest nerve involved. Few patients reported lepra reaction and adverse drug reaction. Most of the participants (88.7%) were released from treatment following completion of MDT.

Evaluation of leprosy programme using selected indicators has been mentioned in Table 3. New cases detection rate was calculated for the period 1st October 2017 to 30th September 2018 for this study as 2.6 per 1 lakh population. Various

other rates calculated was Female rate 32.6%, Child rate 6.75%, Multibacillary rate 93.3% and Grade 2 disability rate 11.2%.

Discussion

The present study has described clinico-epidemiological profile and treatment outcome of leprosy cases as per recent National Leprosy Eradication Programme along with evaluation of leprosy program using certain indicators. The current study found that majority of study participants were males (60) with male female ratio of 2.07:1. Similar observations have been noted by other studies in India regarding gender distribution of leprosy cases. In a study conducted by Vlassoff et al (1996), in Maharashtra & Bihar ratio of male: female was 1.7:1. The age of the study subjects ranged from 10 years to 75 years, with mean age being 35.7 years. It showed that leprosy affects all ages from childhood to elderly. The findings were consistent with other studies. In study by Williams et al (2019) at Ludhiana, Punjab the mean age at presentation was 32.74±13.03 years. Education status of the current study subjects showed that majority of the subjects (54%) were illiterate or educated up to primary school. In a study conducted by Gautham et al (2011) at Chamrajanagar, Karnataka 50.2% of the study participants were illiterate.

In this study only 1.1% of the participants had a history of contact with an active case of leprosy or presence of an active case of leprosy in family which may be explained by low prevalence rate of leprosy in the city. In the current study only 3.4% of the participants had a history of leprosy. This observation is different from that found by Bhat & Chaitra (2013) in their study in Mangalore, Karnataka where 16.36% of patients gave a past history of leprosy. Presence of hypopigmented patch is one of the cardinal signs of leprosy and that is well represented in our finding. Similar findings observed in a study conducted in Mumbai, Maharashtra by Lasri-Levy et al (2011) where 68.3% of patients had presented with skin involvement with patches, nodules, ulcers or infiltration. Current study showed a very high proportion of multibacillary cases (93.3%). A study done in a tertiary care centre in Delhi in 2013 revealed increasing trend of multibacillary cases visiting a tertiary care centre over past decade from 76% to 90% (Singal & Sonthalia 2013) while a similar higher level observed in a study done in 2016 in Ahmedabad, Gujarat (Rathod & Mistry 2016). Though there have been studies where higher (>50%) proportion of MB cases have been observed, the current study showed one of the highest rates recorded across similar studies in India. This trend of MB cases observed seems to have no relation to endemicity of the disease as these regions show differential trend. WHO classification of leprosy cases into paucibacillary and multibacillary has a potential risk of misclassification into wrong types as it is based on clinical examination. High multibacillary rate can also be attributed to late detection of cases in the community. MB cases may increase with a decline in total cases because these are difficult to treat and will cluster in the numerator while denominator decreases. So, with decreasing PR, paucibacillary cases decreases and MB cases are on the increase which suggests decreasing trend of leprosy in the community. In current study the study area is also historically known low prevalent region for leprosy.

In current study 27% participants belong to lepromatous leprosy (LL) spectrum while 3.4% to tuberculoid spectrum following clinical classification of cases as per Ridley-Jopling classification (1966). Rest 70% cases reported as borderline leprosy (BT, BB & BL). Majority of participants in a recent study done by Tegta et al (2019) in a tertiary care centre in Shimla, HP belonged to BL, LL & BT similar to findings in our

study. In the current study it was observed that 25.8% participants had grade1 disability and 11.2% had grade2 disability. Disability of one or both hands was much more common than disability of one or both feet or disability of both hands & feet.

Most common visible deformity was claw hand in the current study. A study conducted by Thakkar & Patel (2014) in Gotri, Vadodara observed disabilities in 42.8% of patients which comprised 29.2% patients of grade 1 and 13.6% of grade 2 which is slightly higher as compared to the current study. Other studies too have observed involvement of hands & feet leading to disabilities but most of the studies (Tegta et al 2019) mentioned the presence of disability and not their distribution as per site of deformity. However, in a study conducted by Asia et al (2015) in Akola, Maharashtra mentioned the site of deformity with majority of study participants having disability of one or both hands (63.4%) followed by one or both feet (29%) and rest with disability of multiple sites. In most of the studies claw hand was the most common visible deformity as observed in the current study. Grade 2 disability rate is quite high signifying late detection of cases in the community. Migration, abundance of pockets of urban slums, poor awareness about early signs of disease and stigma may be the factors responsible for late detection of cases in the community.

In the current study, most common nerve involved was ulnar nerve followed by lateral popliteal, median, post tibial & radial nerve. Majority of the cases in the current study showed multiple nerve involvement at the time of examination. Ulnar nerve was the most common nerve affected (70%) followed by lateral popliteal nerve in a study in Akola, Maharashtra

by Asia et al (2015). In a study in Maharashtra under Bombay leprosy project by Lasry-Levy et al (2011) nerve enlargement was present in one nerve in 30.4% patients and in multiple nerves in 69.6%. Ulnar nerve is the most common nerve to be affected in leprosy and our study findings have been collaborative to it. Nerve damage leads to various sensory alterations such as numbness and motor alterations which lead to varying degrees of physical disability affecting the social and economic life. This explains claw hand being the most common visible deformity observed in this study or previous studies.

In current study majority were released from treatment (88.7%) after completion of MDT while rest could not complete treatment due to various reasons. Comparable results have been observed in a study in Satara, Maharashtra by Mohite & Durgawale (2011). As per latest NLEP data released the proportion of cases released from treatment as cured in Maharashtra is 97% which is higher than in the current study (NLEP 2019). NLEP recommends that released from treatment of above 95% is desired for favourable impact of the programme in an area and to achieve eradication of the disease. The study place is an urban area with good quality of living, so migration is an important factor which may explain the comparatively lower percentage of cases released from treatment. In the current study most of the cases had no history of lepra reaction at presentation or throughout the follow up period while 12.4% had type 1 lepra reaction mainly at diagnosis and none of the patient had type 2 lepra reactions. In a similar study conducted by Asia et al (2015) in Akola, Maharashtra 19% of the participants had type 1 reaction at presentation while type 2 reaction was present in 9.25%. However, a study conducted

at Shimla, HP by Tegta et al (2019) found 37.1% cases with lepra reaction, out of which 56% cases were of type 2 reaction.

Annual new case detection rate in this study area was calculated at 2.6 per 100,000 population. Pune is historically a low prevalent region of western Maharashtra with low new case detection rate. Over past decade the new case detection rate in the area was recorded below 10 per 100,000 population. It is well below the current ANCDR of Maharashtra state of 12.89/100,000 and overall, India figure of 10.17/100,000 as per latest NLEP report (NLEP 2019). Majority of the studies have shown decline in trend of new case detection rate over the years. The explanation for such low rate in the current study could be the fact that there are not much leprosy cases in the region or there is a need to adopt new strategies to detect these cases as early as possible. Female rate is the proportion of female cases among new cases. In the current study female rate was calculated to be 32.6% while present female rate of leprosy in Maharashtra is 45.11% while that of India overall is 39.17% as per latest NLEP report of 2017-18. In the current study the female rate is significantly below the state and India rate which can be explained by preponderance of migration among male gender to an urban area. Child rate is the proportion of child cases <15 years of age among new cases. In the current study child rate was calculated to be 6.75% which is below the current India & Maharashtra child rate of 8.7% and 10.18% respectively. Child rate is an indicator of presence of active infection in the community and thus a low child rate represents a positive impact of NLEP in the region. Multibacillary rate is the proportion of multibacillary cases among new cases. In the current study multibacillary rate was calculated to be 93.3% which is surprising if we compare to majority of the

similar studies done in the past. High number of multibacillary cases in the community is also an indirect reflection of late detection of cases in the community. In this study 65.2% of cases were detected by self-reporting, 17.9% by active screening and 16.9 through referral from other health centres. Grade 2 disability rate is the proportion of grade 2 disability cases among new cases. In the current study grade 2 disability rate was calculated to be 11.2%. This disability rate is higher as compared to disability rate of the study area over past decade (NLEP 2019a), however, is comparable to similar urban areas (Rathod & Mistry 2016). It was much higher as compared to latest disability rates of India overall figure of 3.61% and Maharashtra state of 2.76%. Prevalence rate was not calculated in this study as only new cases during study period were included in the study. Treatment completion rate was also not calculated for this study as it is calculated using cohort analysis method which requires leprosy data of previous years separately for paucibacillary and multibacillary cases, which is not part of this study methodology.

Limitations

No trend analysis could be done for various indicators in the current study for a better evaluation of NLEP in the study area over the years. As the current study is longitudinal descriptive in design it does not allow cause and effect relationship to be established between the variables.

Conclusion

The findings of the study provide an insight into the clinico-epidemiological profile of the leprosy patients as well as give brief evaluation of the NLEP in the study area. High percentage of multibacillary cases among new cases is an indicator of late detection of cases in the community. High grade 2 disability rates also suggest late reporting. The

study area is a predominantly urban population with high percentage of migrant population. It is recommended that NLEP in the region should target urban slum pockets and other foci of high prevalence areas for hidden cases in the community. Active case finding with IEC activities targeting migrant population pockets and unauthorized urban slums will help in early detection of these cases. Role of NGOs, self-help groups & volunteers are also important in this regard. Few of the individuals during the study found to have refused treatment. It is recommended that further efforts should be made by the government for guidance and empowerment of leprosy cases to reduce the stigma attached to disease. Continuous monitoring and evaluation of national program at all regions within India is essential to eradicate leprosy.

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