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Original Article

A Five Year Retrospective Study of Profile of Leprosy Patients in a Teaching Tertiary Care Centre in Uttarakhand

K Joshi[1], G Rizvi[2], A Kaushik[3], U Joshi[4]

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Despite India reaching elimination levelsas a public health problem, leprosy still remains a major health care problem. The aim of our study is to determine the morphological pattern and the trend of acid-fast bacilli (AFB) positivity of the disease in the post eradication phase. A retrospective study was conducted of skin biopsies clinically diagnosed as leprosy from January 2015 to December 2019. Relevant clinical history was obtained from records. Majority were in the age group of 31-40 years (20%), with male predominance (61.25%). 10.62% cases were of children below the age of 15 years. Histologically, 38.75% of cases were diagnosed as indeterminate leprosy followed by 20% cases of lepromatous leprosy. Hypopigmentation (35.62) was the most common clinical feature. Clinical-histological concordance was highest for histioid leprosy cases (100%) followed by lepromatous leprosy (90.62%). Majority of our cases were multibacillary (71.25%). BI 1+ was seen in 51.75%, whereas BI 6+ was 11.4%. Predominance of multibacillary forms specially with high bacterial load indicates late reporting and need to diagnose and treat early for stopping its transmission. Histopathological examination of skin biopsy is important for early and proper treatment of the patients with early inderminate/atypical clinical manifestations. The health care policies need to be reconsidered and revised both at the national and global levels.

Keywords : Leprosy, Histopathology, Elimination, Bacteriological Index

Introduction

Leprosy is a chronic infectious disease caused by *Mycobacterium leprae* which was discovered by Gerhard - Henrik Armauer Hansen in Norway in 1873 (Shelly & Shenoy 2018). Lepromatous leprosy [LL] existed in India around 2000 BC. Skeletal evidence was found at Balathal in Rajasthan. Textual reference of the disease is found in the sacred Sanskrit work of Atharvaveda (Robbins et al 2009). Histopathological examination is required to make a diagnosis and classify it according to the criteria established by Ridley and Jopling (1966). This classification takes into account the histological features, and the spectrum indicates the immune status of the patient. In India and Africa, Tuberculoid leprosy [TT] is predominant, accounting for 90% of cases (Gelber 2005). In 1991, World Health Assembly

[1] Dr Kriti Joshi, MBBS, Junior Resident III
[2] Dr Ghazala Rizvi, MD, Associate Professor
[3] Dr Ankit Kaushik, MD, Assistant Professor
[4] Dr Usha Joshi, MD, Associate Professor
Department of Pathology, Government Medical College, Haldwani- 263139, Nainital, Uttarakhand, India
Corresponding Author : Dr Ghazala Rizvi, **Email :** ghazalarizvi1970@gmail.com

had resolved to eliminate leprosy globally by 2001. In December 2005 India declared that leprosy had been eliminated at the national level. Sadly that is not in reality. The largest number of cases of leprosy in South East Asia region are contributed by India and Indonesia with 120334 and 17017 cases respectively (WHO 2019). As recent as 2015 the highest incidence of leprosy was seen in India (127,326 cases), Brazil (26,395 cases) and Indonesia (17,202 cases). We were unable to achieve the ambitious goal set by World Health Organization (WHO) in 1991 of eliminating leprosy by 2000 despite the numerous National Health programs (Fischer 2017). India is currently running one of the Largest National Leprosy Eradication Program (NLEP) in the world. Despite these herculean efforts 120,000 to 130,000 new cases are reported every year from our country (Sengupta 2018). At the end of 2005 Govt of India declared that the country was free from leprosy as a public health problem, which technically implies that less than 1 person in 10,000 is affected by the disease. After this the programme was incorporated into general health care services. Though the percentage appears to be low, the number is still significantly high in absolute terms, contributing to 58.8% of the global new cases. The WHO composite index for leprosy, which is based on prevalence, new case detection rate, grade 2 disability rate and the percentage of child cases, has placed India among the top 22 countries globally for a high burden of the disease as well as high transmission (Rao 2017). According to the NLEP 1,35,485 new cases were detected in 2016-17, which puts the Annual Detection rate at 10.17 per 10,000. The prevalence rate of leprosy in Uttarakhand state was 0.22 per 10,000 population as on March 2014 (Dimri 2016). The present study was conducted to determine the morphological pattern and the trend of Acid-fast bacilli positivity of the disease in the post eradication phase in a tertiary teaching hospital of Kumaon region of Uttarakhand and to also to reflect on the possible shortcomings which might be responsible for the failure in eradicating the disease in the true sense.

Materials and Methods

The present study is a retrospective analysis of all the biopsies clinically diagnosed as leprosy received in the Department of Pathology, Government Medical College, Haldwani, Nainital over a period of five years from January 2015 to December 2019. Clinical history and patient details and clinical diagnosis were collected from the records record. The biopsy samples underwent routine tissue processing, and all cases were stained with Hematoxylin & Eosin and Acid-fast staining, followed by histopathological examination. The cases were categorized according to classification given by Ridley and Jopling (1966). The Bacteriological Index (BI) was graded according to Ridley's logarithmic scale of 1 to 6 ased on the number of acid-fast bacilli seen using an oil immersion objective.

Results

A total of 160 cases of leprosy were evaluated from 2015 to 2019. Males constituted 61.25% of the total cases. Histopathologically, inderminate (IL) (62 cases; 38.75%) constituted the major group followed by - lepromatous (LL) (32 cases; 20.00%), borderlinetuberculoid (BT) (29 cases; 18.12%), tuberculoid (TT) (17 cases; 10.63%), borderline lepromatous (BL) (12 cases; 7.5%), mid borderline (BB) (4 cases; 2.5%) and histoid-HL (4 cases; 2.5%) (Fig. 1).

Tuberculoid leprosy accounted for 10.62% (n=17) cases. Among them, 8 cases showed Giant cells along with granulomas 4 showed only granulomas, and 5 showed endoneuritis.

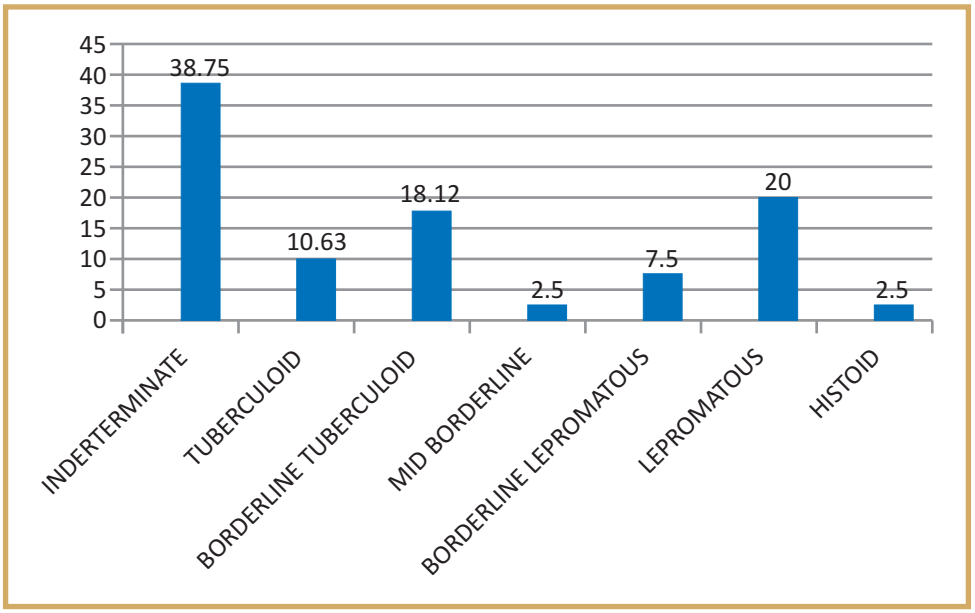

Fig. 1 : Distribution in % of cases according to the Ridley Jopling classification of leprosy

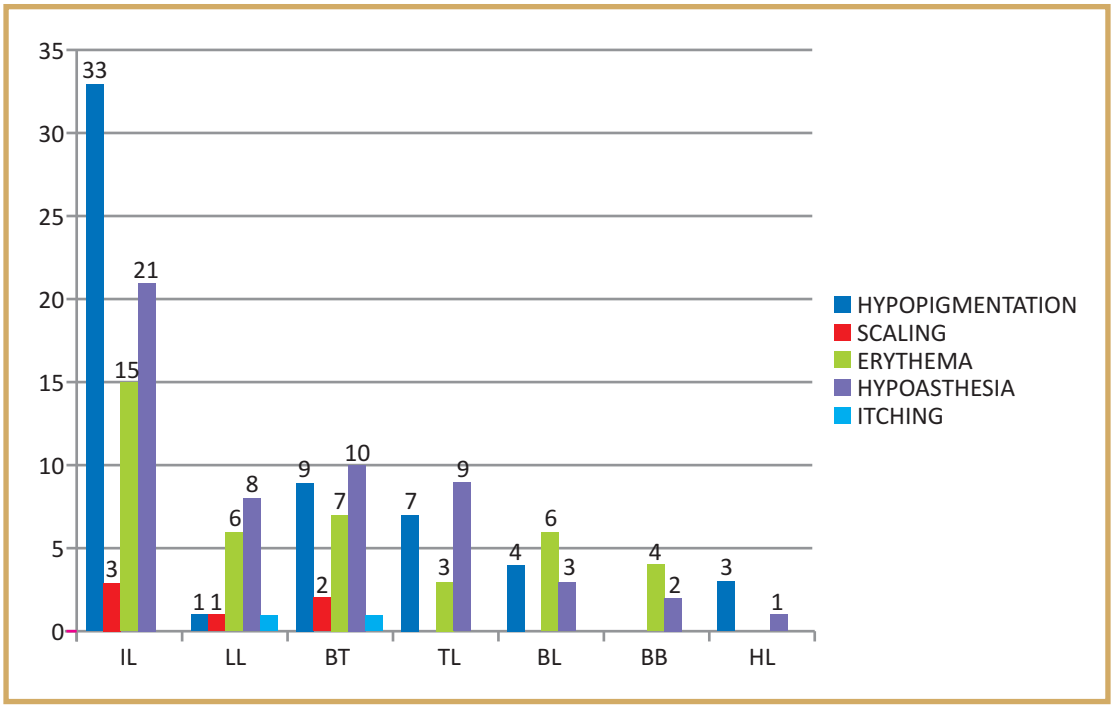

Fig. 2 : Types of leprosy according to clinical presentation

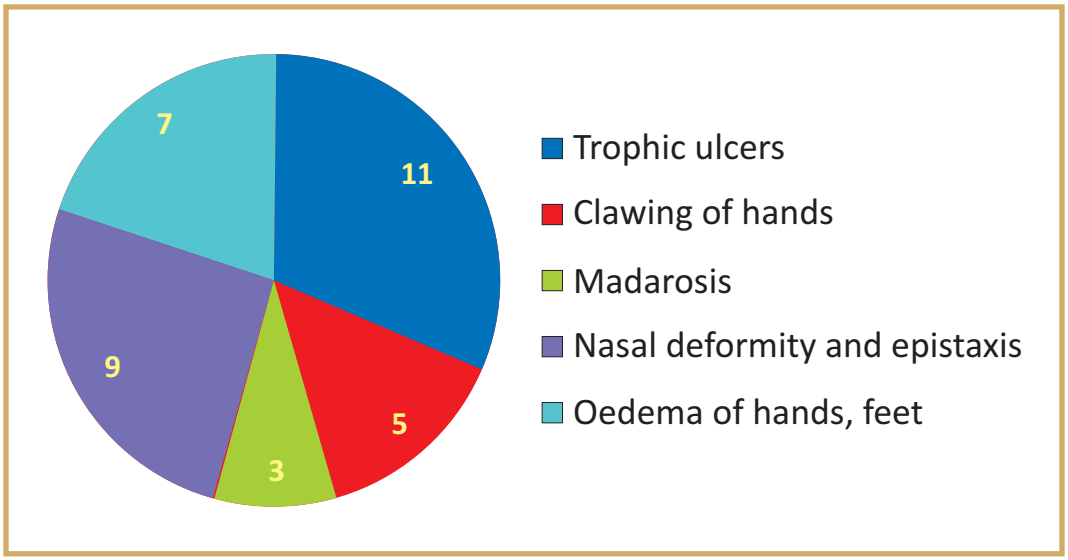

Fig. 3 : Distribution of secondary disabilities

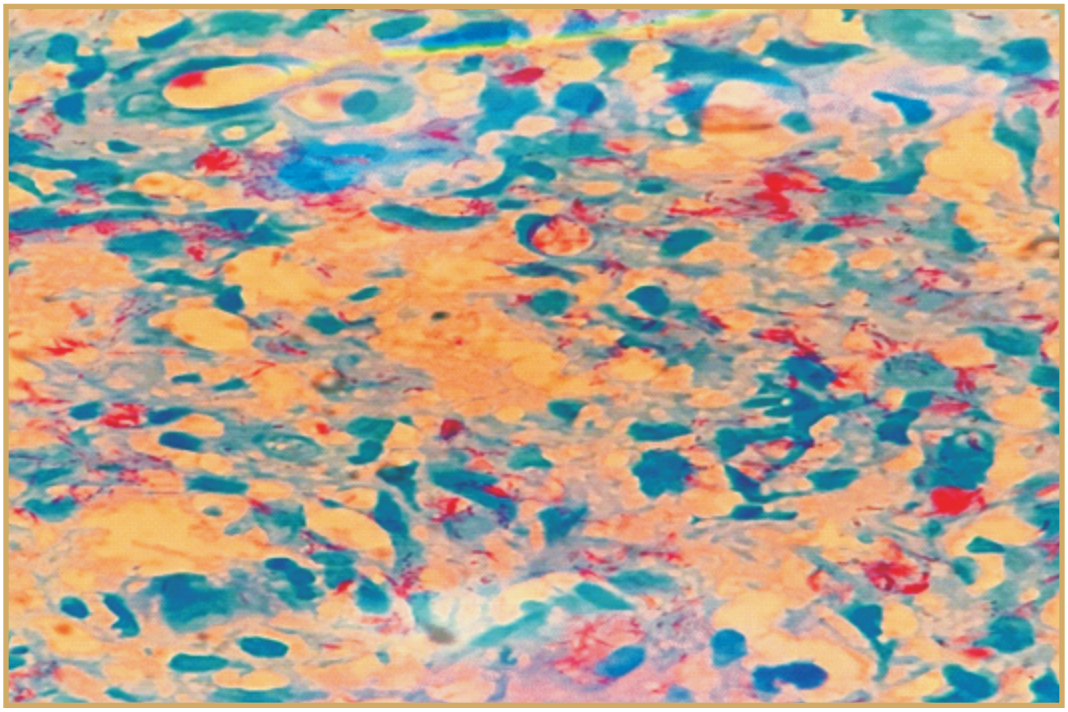

Fig. 4 : Globi of bacilli in biopsy section of Lepromatous leprosy with B.I of (6+)
(Wade Fite stain in oil immersion field X 1000)

Age wise distribution of these cases is summarized in Table 1. Maximum number of cases were seen in the age group of 31-40 years (32 cases; 20.00%) followed by 11-20 years (29 cases; 18.12%), 51-60 years (27 cases; 16.89%), 21-30 years (26 cases; 16.25%), 41-50 years (26 cases; 16.25%), 61-70 years (16 cases, 10.00%), 0-10 years (2 cases; 1.25%), 71-80 years (1 case; 0.62%) and 81-90 years (1 case; 0.62%) (Table 1) 10.62% cases were of children below the age of 15 years.

Clinically hypopigmentation (57 cases; 35.62%) was the most common clinical feature followed by hypoesthesia (54 cases; 33.75%), erythema (41 cases; 25.63%), scaling (6 cases; 3.75%) and itching (2 cases; 1.25%) (Fig. 2).

Table 1 : Age wise distribution of different types of leprosy

	0-10	11-20	21-30	31-40	41-50	51-60	61-70	71-80	81-90
IL	0	12	8	15	9	11	7	0	0
LL	0	7	6	7	3	7	1	1	0
BT	1	2	6	5	10	0	4	0	1
TT	1	5	1	3	3	4	0	0	0
BL	0	1	5	2	1	3	0	0	0
BB	0	2	0	0	0	2	0	0	0
HL	0	0	0	0	0	0	4	0	0

Table 2 : Distribution of cases showing nerve involvement

Nerve involved	Number of cases	Percentage
Ulnar nerve	27	16.90%
Lateral popliteal nerve	06	3.75%
Radial nerve	10	6.25%
Combinations of nerves	19	11.90%

Table 3 : Clinical-histological concordance

Types of Leprosy	Clinical-Histological Concordance [N (%)]	P Value [Significant if More Than 0.05]
Indeterminate[62]	37(59.67%)	0.127
Lepromatous[32]	29(90.62%)	0.000004
Borderline Tuberculoid [29]	13(44.82%)	0.577
Tuberculoid [17]	5(29.41%)	0.089
Borderline Lepromatous[12]	5(41.66%)	0.563
Mid Borderline[04]	1(25%)	0.317
Histioid[04]	4 (100%)	1.000
Overall corcordence [160]	94 (58.75%)	

Table 4 : Distribution of cases according to Bacteriological Index on Acid Fast Staining

Histopathological Type	Bacteriological Index						
	Paucibacillary	Multibacillary					
	0	1+	2+	3+	4+	5+	6+
IL (62)	7	55	0	0	0	0	0
TT(17)	14	3	0	0	0	0	0
BT(29)	25	1	3	0	0	0	0
BL(12)	0	0	0	1	6	5	0
LL(32)	0	0	0	0	2	17	13
BB(4)	0	0	0	2	2	0	0

Table 5 : Comparison of Bacteriological Index (BI) with other studies

Study	B.I. 1+	B.I. 6+	Total Positivity
Patil et al (2020)	41.25%	0.62%	100.00%
Premalatha et al (2016)	26.66%	6.66%	70.00%
Ansari et al (2020)	11.30%	4.80%	20.96%
Kilikdar et al (2018)	12.64%	11.49%	34.66%
Present study	51.75%	11.4%	34.37%

The ulnar nerve was the most commonly affected nerve accounting for 27 cases presenting with nerve involvement (Table 2).

Among secondary disabilities, trophic ulcers (11 cases; 6.90%) were seen in maximum number of cases followed by nasal deformity and epistaxis (9 cases; 5.62%), oedema of hands and feet (7 cases; 4.37%), clawing of hands (5 cases; 3.12%) and madarosis (3 cases; 1.90%) (Fig. 3).

The overall association between the clinical and histopathologic diagnosis of types of leprosy was 58.75%, - highest for histoid leprosy, followed by leptomatous leprosy (Table 3).

In our study, no acid fast bacilli were demonstrated in 46 cases (28.75%), while 114 cases (71.25%) were positive for acid fast bacilli (Table 4).

Out of the 114 cases, 59 (51.75%) cases showed BI 1+ whereas 13 (11.4%) cases showed BI 6+ (Fig. 4).

Discussion

Though the prevalence rates in India have shown a tremendous decline from prevalence rate of 57.8/10,000 in 1983 to less than 1/10,000 by the end of 2005, the new case detection rate has remained almost constant over the last 15 years. For those living in endemic areas - hygienically inadequate living conditions, contaminated water, insufficient diet and any disease that leads to compromised immune function are the risk factors for acquiring *M. leprae* infection (Bhat & Prakash 2012). Our study showed a male predominance (61.25%) in the patients. Similar results were seen in the studies conducted by Thakkar & Patel (2014), Chhabra et al (2015), Jain et al (2002), Rawat et al (2017), Giridhar et al

Table 6 : Comparison of our study with other similar studies in the country

Study with year and place	Total Number of Cases	Sex [%]	Most Common Age-Group Affected	Most Common histopathological type [%]	MB Cases using Ridley's bacterial index (BI) as the criterion (%)	G2D (%)	Paediatric Cases (%)
Tegta et al (2019, Shimla)	221	Males [73.3%]	15-30 (38.5%)	LL (32.1%) BL[31.2%]	85.5	74.66	2.3
Dimri et al (2016, Garhwal)	129	Males [62.8%]	18-60 (83.7%)	-	50.38	-	6.9
Giridhar et al (2012, Punjab]	98/100	Males [77.6%]	21-30 (41.8%)	BT (42.86%) IL(18.37%)	29.59	-	-
Rawat et al (2017, Dehradun)	238	Males [78.6%]	17-40 (54.6%)	BT(39.5%) BL(26.5%)	81.9	21.8	2.1
Praba & Narmadha (2019, Tamil Nadu)	154	Males [61.68%]	21-30	LL(26.6%) BL(25.3%)	-	65	-
Garg et al (2018, Haryana)	60	Males [61.7%]	21-30 (30%)	BL(21.7%) BT(20%)	61.7	38.3	-
Sharma & Rai (2018, Rajasthan)	158	Males [64.6%]	21-40 (46.2%)	IL(32.2%) BL(17.7%)	-	-	7.5
Adil et al (2018, Aligarh)	225	Males [67.6%]	31-40 [26.7%]	BL(38.2%) LL(28%)	70.2	-	14.2
Kilikdar et al (2018, Maharashtra)	174	Males [68.96%]	21-40 [57.47%]	-	58.62	38.5	-
Thyvalappil et al (2019, Kerala)	133	-	-	-	57.9	9.3	14.3
Gupta et al (2019, Bihar)	464	-	-	-	80.17	20.6	5.6
Chudasama et al (2016, Gujarat]	207	-	-	-	58.94%	-	-
Dubey et al (1981	100	-	-	LL(58%) TT(20%)	-	-	-
Jain et al (2002, Hyderabad)	306	Males [60.00%]	0-14 (100%)	BT(66.3%) TT(20.3%)	-	-	100%
Present Study Nainital	160	Males [61.25%	31-40 (20%)	IL(38.75%) LL(20%)	71.25	38.75	10.62

(2012). The main reason for this is that males have greater outdoor activity, therefore, a greater chance of being exposed to cases of leprosy. Also, males have greater access to health care facilities than the opposite gender due to the social customs and, therefore, more detection of the disease in them. IL accounted for the largest number of cases in our study (38.75%, n=62) followed by LL (20%, n=32). Similar results were reported by Sharma & Rai (2018) (30.9%). Contrary to our study, Kaur et al reported LL as the most common histopathological type whereas Mathur et al and Gangwar et al reported TT as the commonest type in their study (Kaur et al 2009, Mathur et al 2011, Gangwar et al 2017). IL is characterized by superficial and deep dermal infiltrate around blood vessels and dermal appendages and nerves, composed predominantly of lymphocytes and macrophages. Demonstration of acid-fast bacilli is mandatory for diagnosis otherwise, it's a presumptive diagnosis based on the clinical features only. Because of non-specific morphological features and low bacillary index, there is a fair possibility of over-diagnosis, especially if the clinician has a strong index of suspicion for the disease.

The second most common type was LL accounting for 20% of cases (n=32). A large proportion of LL may indicate late detection. Though the socio-demographic profile of these patients was not taken into account in this study, factors like inadequate nutrition and lack of proper residential facilities, especially density of home occupancy, may be contributing factors for the disease as most of our patients referred are from adjoining rural areas or are the workers from the paper factory situated about 10 km from our hospital.

Maximum patients belonged to the age group of 30-40 years. Similar observations were also reported by Gupta et al (2019), Veena et al (2011), Relhan et al (2016), Hazarika et al (2017), Gangwar et al (2017) and Kulkarni (2016). The increased vulnerability of patients in this group may be due to greater mobility for work and therefore increased opportunity of being in contact with a larger segment of the population which would mean greater exposure and chance of contracting an infection (Gupta et al 2019). Getting a large proportion of cases in the adult population would also imply that there has been a stable incidence rate among the adults in the region for a considerable period of time before this study was conducted. Another explanation is that *M. leprae* has a very long incubation period and multiplies slowly. During this long incubation period, there are no available serologic or biologic methods to demonstrate the presence of sub-clinical infection in the patient.

Our study showed that 10.62% (n=17) of patients were below the age of 15 years. Tiwary et al (2011) and Relhan et al (2016) reported similar findings, with 10.20% and 7.59% pediatric cases, in their study. Whereas, Gupta et al (2019) reported 5.60% pediatric cases. Leprosy in children is an indirect reflection of the existence of a pool of undiagnosed cases in the community. As long as this small but significant pool of pediatric cases exists the transmission chain stays alive. The plausible reason for the failure to detect these young patients may be that it's challenging to not only assess sensory loss in children, very few will even complain of it (Narang & Kumar 2019). The increasing rate of female literacy, the change in social customs which now allow females to venture out of their homes alone and the fact that working females are now financially independent may also be important factors that contribute to children having an access to health care services and therefore a substantial number of cases being detected in this age group.

Among the presenting symptoms, hypopigmented patch was the commonest complaint as it is easily noticed by the patient, and due to cosmetic reasons the person seeks medical help early. Similar finding was reported by Giridhar et al (2012) majority of the patients that presented with hypopigmented patches (20.6%, n=33) were diagnosed as IL, however, hypoesthesia was the commonest complaint in patients diagnosed as LL and TT.

In our study, the highest clinical-histological concordance was seen with histoid leprosy [HL] (100%) followed by LL (90%). Sharma et al (1997) reported similar findings (clinical-histological concordance of 75.86% with LL). Singh et al (2000) reported a concordance of 100% for LL+HL, 83.02% for TT+BT, 80.77% for BL+HL, 73.91% for BL+LL and 72.58% for BT+BB+BL. Semwal et al (2018) had a 100% correlation with TT, HL and Erythema nodosumleprosum [ENL], 44.8% and 47.3% with borderline tuberculoid [BT] and borderline lepromatous [BL], respectively. Soniet al (2018) reported a 100% concordance with HL, IL and Type I leprareaction followed by 87.5% concordance with ENL, whereas, no concordance was seen with BB and BL.

The discrepancy between the clinical diagnosis and histopathological subtype can stem from the fact that the diagnostic category assigned to the disease is based purely on presentation with the histology categorization still in waiting. Histological diagnosis is influenced by factors like-depth and adequacy of the biopsy sent, site from where it is sent, duration of the disease, quality of the sections, criteria being used to select the patient for skin biopsy, changing immune status of the patient as well as when the clinical phase of the disease. Besides, these, inter-observer variation exists in all settings. With HL and ENL the symptoms are almost diagnostic of the disease, and therefore these subtypes have a high concordance rate. With borderline and indeterminate leprosy, a high index of clinical suspicion is required.

Neuropathies are common in leprosy as *M. leprae* is primarily an intracellular neurotropic bacterium targeting the schwann cells and neurovascular bundles with a predilection for peripheral nerves rather than deep ones. Sensory loss is the cardinal symptom of leprosy neuropathy. In our study, ulnar nerve was involved in maximum cases (n=27), whereas polyneuropathy was seen in 19 cases.

BI is probably the only unbiased way of assessing the benefit of treatment. It denotes the density of leprae bacilli, both living (solid staining) and dead (fragmented or granular). In our study multibacillary leprosy (71.25%) far exceeded paucibacillary leprosy (28.75%). Kilikdar et al (2018), Rathod & Mistry (2017), Mowla et al (2015) and Arora et al (2008) have reported findings similar to our study. However, contrasting results were observed by Patil et al (2020) where paucibacillary cases (53.62%) were more than multibacillary cases (46.38%). The high percentage of multibacillary cases in our study is a subject of concern as a high bacillary load means high infectivity and an equally high rate of transmission. Comparison of the BI with other studies is shown in Table 5.

Leprosy is a disease with a long incubation period ranging from 2 to 20 years. It is shed from the nasal mucosa of untreated leprosy patients. Being a resilient organism, it can survive outside the body for up to 45 days. Patients newly diagnosed with leprosy may have transmitted the disease long before their disease is detected. For a disease with such complex epidemiological and biological background, elimination by just multidrug therapy alone is a challenging task. Prevalence rate of <1/10,000 appears to be very low, but, in countries with a high population

density like ours, in absolute numbers, it would still amount to a significant number of cases. In our study, 20% of cases were of LL and this group of patients with high bacillary load are probably responsible for keeping the infection alive in the community. With 10.6% pediatric cases in our study, it is evident that the chain of transmission has not been broken in the community. The results of our study clearly indicate the concept of "elimination" of leprosy needs to be reassessed. The disease should be viewed as a chronic disease and the emphasis should shift to long term planning in order to control number of new cases and offer effective sustainable care to the patients. A surveillance system needs to be put in place by the health services to avoid missing new cases and identify existing ones to prevent transmission of the disease. For this the government may need to pull away the leprosy programs away from the vertical specialized programs and integrate it with the primary health care centers who actually diagnose and treat these patients. For this surveillance to be effective, the concerned workers need to be trained first. Non-governmental organizations [NGO], who have previously been involved with the vertical programs can also be used for this purpose. Also there should be an adequate number of primary health care centers available in the region/ state. In our country that could be a limiting factor; for example, in Bihar there is only one health care facility/200,000 population, whereas in South India, the figure is 1/30,000 population (Krishnamurty 2004). In the hilly regions of Uttarakhand, this could be a major obstacle in controlling the disease and preventing transmission. Though our country has been declared leprosy freeway back in 2005, we should not become complacent about the disease (Rao & Suneetha 2019). A timely diagnosis and adequate treatment of the patients should now be the new goal. This will help to reduce the source of infection and maybe break the chain of transmission in the community.

Conclusion

Though our study covers a period of mere five years, it does show that we haven't really bidden adieu to this disease yet. A timely, accurate diagnosis and appropriate treatment are critical for controlling the transmission of the disease. The fact that new cases, especially pediatric cases, are being detected signifies that the transmission chain is very much alive and needs to be interrupted. The health services need to look back to analyze their shortcomings. New goals now need to be defined both at the national and global level to control, if not eradicate the disease.

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