Determinants of patients' delay with disability in the diagnosed leprosy cases in the three major states of India: A case-control study

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Abstract

Background: Skin lesions are the most common early symptoms of leprosy, often ignored by patients at an early stage and misdiagnosed as other dermatological diseases by healthcare personnel, leading to delay in diagnosis and treatment of leprosy precipitating permanent neurological deficit, deformities and serious disabilities.

Aims: The objective is to evaluate the duration of delay and factors responsible for the delay in reporting of patients, among the newly detected leprosy cases (Grade 1 and Grade 2 disability patients).

Methods: A case-control study was conducted during 2014–2016 in three major states of India (Delhi, Gujarat and West Bengal) in 140 randomly recruited newly registered adult leprosy patients (aged 18 years and above) with Grade 2/1 disabilities (cases) and 140 Grade 0 disability patients (controls) in each of these Indian states.

Results: It is established that the major contributors for the delay in the early diagnosis of leprosy have been patient-related factors. The median patient delay in the three states of Delhi, Gujarat and West Bengal were five months (0.7–1.8), 2.8 months (2–14) and 12 months (2–24), respectively.

Limitations: The study design is case-control and has an inbuilt reporting bias due to the retrospective nature of data collection but the data collection was carried with caution to reduce the recall bias. As the study is carried out in three states, generalisation of interpretation was cautiously executed. The matching ratio of cases and controls was 1:1 in this study, but we could not increase the controls due to operational feasibility during the conduct of the study.

Conclusion: Patient delay is a crucial factor responsible for the disability among new leprosy cases. A higher patient delay in these three states reflects that the community is not aware about the signs and symptoms of leprosy. Reducing patient delay is very important for reducing disabilities in the newly diagnosed cases.

Keywords: Case-control study, delay, leprosy, patient delay, risk factors

Plain Language Summary

Leprosy is the world's oldest recorded disease and is caused by the bacteria *Mycobacterium leprae*. It affects the nervous system, especially the nerves of the hands, feet and face, and is the leading infectious cause of permanent disability. It is curable, but left untreated it can cause nerve damage, loss of feeling, paralysis and blindness. The clinical spectrum of disease range is wide from tuberculoid to lepromatous leprosy which is a result of variation in the cellular immune response of the host to the mycobacterium. Patients often ignore skin lesions at an early stage, leading to the delay in the diagnosis and development of disability. India contributes to more than 60% of the global leprosy disease burden and accounts for about 37% of Grade 2 visible disability. This

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study aimed to quantify the risk factors for disability among the newly diagnosed leprosy patients in selected three endemic Indian states. We found that patient delay was a significant factor responsible for the occurrence of disability among new leprosy cases. The poor community awareness of the signs, symptoms and ignorance of leprosy resulted in delayed diagnosis. Thus, to prevent disability and interrupt transmission of infection it is important to address patient related factors.

Introduction

National Leprosy Eradication Programme was decentralised and linked to primary healthcare set up in India in 2005 with an official declaration, 'Leprosy eliminated as public health problem,' yet India continues to report about 60% of the global cases.[1,2] India alone contributes to 37% of the world's Grade 2 disability cases and 65% of the south-east Asia region.[1] Besides the number of new leprosy cases and the number of Grade 2 disability, other indicators of leprosy such as the number of new leprosy cases in children and the number of Grade 2 disability among children are being reported in significant numbers from India. This increased reporting of new leprosy cases in children under 15 years of age and initial presentation of patients with Grade 1 disability and Grade 2 disability implies that the various factors such as lack of awareness, stigma, health-seeking behaviour and other determinants are responsible for the patient delay in the diagnosis and treatment of leprosy.[3-5] Besides patients' delay, failure of the healthcare system in identifying the cases is also a major contributing factor, [6-8] However, here in this paper, the duration of the delay and factors responsible for patient delays in three Indian states of Delhi, West Bengal and Gujarat, is evaluated.

Methods

A case-control study was conducted in three major states of India: Delhi, Gujarat and West Bengal, between August 2014 and July 2016, using two-stage cluster sampling, the first stage identifying the three districts and at the second stage, cases and controls were selected from the National Leprosy Eradication Programme treatment registers, randomly.

Cases were defined as adult leprosy patients, aged 18 years and older at the time and registered for the treatment under National Leprosy Eradication Programme with Grade 2 or Grade 1 disability (WHO definition). Controls were defined as adult leprosy patients, aged 18 years and older at the time and registered for the treatment under National Leprosy Eradication Programme with the WHO Grade 0 disability. The WHO grading system of leprosy Grade 0, Grade 1 and Grade 2 disability was used in the selection of cases and controls.[9]

A sample size of 135 cases and 135 controls (1:1) was estimated, based on the probability of exposure to one of the main risk factors (poor knowledge/low awareness of disease) as 20% and an anticipated odds ratio of 2 with the power of 80% and an alpha error of 5% for one-sided test. Hence, for this study, it was decided to select 140 cases and 140 controls. Homogeneity among 140 cases was achieved by selecting 70 Grade 2 disability cases and 70 Grade 1 disability cases.

From the National Leprosy Eradication Programme registers maintained in the three districts of each state, 140 cases and 140 controls, respectively, fulfilling the selection criterion were selected by a simple random sampling method. While sampling, if a selected case or control was not available, the next registered eligible case or control was selected, respectively. Ethical approval for this study was obtained from the German Leprosy and Tuberculosis Relief Association, Institutional Review Board, India. Necessary permission from the health department of the three states was also obtained. Informed consent from all the participants was obtained before the data collection.

'Patient delay' was defined as the time between the first symptom noticed and the first visit to any healthcare provider. Healthcare provider delay was defined as the time between the first visit to any healthcare provider and the confirmation of the diagnosis of leprosy.

A pre-tested questionnaire in the local languages Hindi, Gujarati and Bengali for each state was used to record sociodemographic, information on patient delay and healthcare provider delay from all the participants. Information on demographics (variables) specific to patient delay and healthcare provider delay was obtained that included age, gender, employment, education, and marital status. Information on patient delay included the occurrence of first noticeable symptom, how did it got noticed, duration between first symptoms and first contact with a qualified doctor and reason for waiting before consulting a doctor, if any. All the time duration in the questionnaire, about the patient delay and healthcare provider delay, were recorded in months.

All data obtained were anonymised and analysed. Percentages calculated for discrete variables and median calculated for continuous variables with interquartile ranges.

Results

A total of 140 cases and 140 controls were interviewed in each of the three states. Sociodemographic characteristics and leprosy type among the cases and controls in the three states are presented in Table 1.

The proportion of men and women was comparable; a high proportion of cases and controls were literate and younger than 30 years in all three states. It was observed that only 10% of cases and about 15% of all controls had a comprehensible knowledge of leprosy. In all three states excepting Gujarat, most of the cases (60%) reported a patient delay of more than six months compared to controls. The proportion of multibacillary leprosy was more among cases (96%) than

Table 1: Patient characteristics and factors related to delay among cases and controls in three Indian states

Variables	Delhi				Gujarat				West Bengal			
	Cases (*n*=140)	Controls (*n*=140)	Crude OR (95% CI)#	Adjusted OR (95% CI)#	Cases (*n*=140)	Controls (*n*=140)	Crude OR (95% CI)#	Adjusted OR (95% CI)#	Cases (*n*=140)	Controls (*n*=140)	Crude OR (95% CI)#	Adjusted OR (95% CI)#
Gender												
Men	109 (78%)	114 (81%)	1.0	1.0	91 (65%)	90 (64%)	1.0	1.0	80 (57%)	78 (56%)	1.0	1.0
Women	31 (22%)	26 (19%)	**1.2 (0.7–2.2)**	0.9 (0.4–2.0)	49 (35%)	50 (36%)	0.96 (0.6–1.6)	**1.1 (0.5–2.2)**	60 (43%)	62 (44%)	0.94 (0.6–1.5)	**1.04 (0.5–2.1)**
Age at diagnosis (in years)												
<30 years	62 (44%)	71 (51%)	1.0	1.0	23 (16%)	39 (28%)	1.0	1.0	43 (31%)	51 (36%)	1.0	1.0
30–60 years	70 (50%)	65 (46%)	**1.2 (0.8–2.0)**	**2.3 (1.2–4.5)**	88 (63%)	92 (66%)	**1.6 (0.9–2.9)**	0.97 (0.5–1.9)	89 (64%)	83 (59%)	0.97 (0.5–1.9)	0.97 (0.5–1.9)
More than 60 years	8 (6%)	4 (3%)	**2.3 (0.7–8.0)**	**2.5 (0.6–11.1)**	29 (21%)	9 (6%)	**5.5 (2.2–13.5)**	**1.04 (0.3–4.0)**	8 (6%)	6 (4%)	1.08 (0.3–4.1)	**1.08 (0.3–4.1)**
Education												
Illiterate	52 (37%)	34 (24%)	**1.8 (1.1–3.1)**	**1.9 (1.01–3.6)**	90 (64%)	84 (60%)	**1.2 (0.7–1.9)**	**1.6 (0.8–3.0)**	80 (57%)	70 (50%)	**1.3 (0.8–2.1)**	**1.6 (0.8–3.1)**
Literate	88 (63%)	106 (76%)	1.0	1.0	50 (36%)	56 (40%)	1.0	1.0	60 (43%)	69 (49%)	1.0	1.0
Marital status												
Unmarried	43 (31%)	33 (24%)	**1.4 (0.8–2.4)**	**2.6 (1.2–5.5)**	19 (14%)	16 (11%)	**1.2 (0.6–2.5)**	**1.3 (0.5–3.4)**	17 (12%)	19 (14%)	0.9 (0.4–1.8)	**1.4 (0.5–3.6)**
Married	97 (69%)	100 (71%)	1.0	1.0	121 (86%)	124(89%)	1.0	1.0	123 (88%)	121 (86%)	1.0	1.0
Locality of residence												
Rural/suburban	30 (21%)	40 (29%)	**1.3 (0.8–2.3)**	0.7 (0.3–1.2)	118 (84%)	123(88%)	1.3 (0.7–2.7)	0.8 (0.1–5.5)	136 (97%)	138 (99%)	**2.0 (0.4–11.2)**	0.9 (0.1–6.2)
Urban	110 (79%)	100 (71%)	1.0	1.0	22 (16%)	77 (55%)	1.0	1.0	4 (3%)	2 (1%)	1.0	1.0
Leprosy type												
Paucibacilliary	6 (4%)	20 (14%)	1.0	1.0	3 (2%)	67 (48%)	1.0	1.0	6 (4%)	42 (30%)	1.0	1.0
Multibacillary	134 (96%)	120 (86%)	**3.7 (1.4–9.6)**	**3.1 (1.1–8.7)**	137 (98%)	73 (52%)	**41.9 12.7–137.9)**	**9.0 (3.4–23.6)**	134 (96%)	98 (70%)	**9.6 (3.9–23.4)**	**8.7 (3.3–22.6)**
Occupation												
Salaried (government/ private)	47 (34%)	67 (48%)	1.0	1.0	7 (5%)	12 (9%)	1.0	1.0	22 (16%)	18 (13%)	1.0	1.0
Daily wage labourer/ agriculture cultivator	60 (43%)	52 (37%)	**2.2 (1.2–4.3)**	**2.3 (0.9–5.9)**	101 (72%)	96 (69%)	**1.2 (0.6–2.3)**	**1.03 (0.4–2.4)**	89 (64%)	93 (66%)	0.8 (0.4–1.6)	0.93 (0.4–2.2)
Unemployed/ housewife/ student	33 (24%)	21 (15%)	**1.6 (0.97–2.8)**	**1.3 (0.7-2.3)**	32 (23%)	32 (23%)	**1.7 (0.6–4.9)**	0.8 (0.3–2.2)	29 (21%)	29 (21%)	0.8 (0.4–1.8)	0.7 (0.3–2.0)
No. of household members												
≤5 members	NR	NR	NR	NR	80 (57%)	71 (51%)	1.0	1.0	33 (24%)	41 (29%)	1.0	1.0
≥5 members	NR	NR	NR	NR	60 (43%)	69 49%	**1.3 (0.8–2.1)**	0.7 (0.3–1.2)	107 (76%)	99 (71%)	**1.3 (0.8–2.3)**	0.7 (0.3–1.2)
Alcohol consumption												
Ever consumed	55 (39%)	58 (41%)	0.9 (0.6–1.5)	**1.4 (0.7–2.5)**	97 (69%)	89 (64%)	**1.3 (0.8–2.1)**	0.9 (0.5–1.7)	54 (39%)	49 (35%)	**1.2 (0.7–1.9)**	0.9 (0.5–1.8)
Never consumed	85 (61%)	82 (59%)	1.0	1.0	43 (31%)	51 (36%)	1.0	1.0	86 (61%)	91 (65%)	1.0	1.0
Distance to the nearest public health facility												
More than 5 km	75 (54%)	61 (44%)	**1.5 (0.93–2.4)**	**1.5 (0.9–2.6)**	77 (55%)	61 (44%)	**1.6 (0.99–2.5)**	**1.2 (0.2–8.7)**	5 (4%)	3 (2%)	**1.7 (0.4–7.2)**	**1.4 (0.2–9.7)**
≤5 km	65 (46%)	79 (56%)	1.0	1.0	63 (45%)	79 (56%)	1.0	1.0	135 (96%)	137 (98%)	1.0	1.0
Messages related to leprosy												
Not heard/ seen/read	123 (88%)	115 (82%)	**1.6 (0.8–31)**	**1.2 (0.6–2.6)**	79 (56%)	103(74%)	**1.6 (0.9–2.9)**	0.7 (0.3–1.6)	113 (81%)	107 (76%)	**1.3 (0.7–2.3)**	0.97 (0.5–1.9)
Heard/seen/ read	17 (12%)	25 (18%)	1.0	1.0	61 (44%)	37 (26%)	1.0	1.0	27 (19%)	33 (24%)	1.0	1.0
Patient delay												

(Contd...)

Table 1: (*Continued*)

Variables	Delhi				Gujarat				West Bengal			
	Cases (*n*=140)	Controls (*n*=140)	Crude OR (95% CI)#	Adjusted OR (95% CI)#	Cases (*n*=140)	Controls (*n*=140)	Crude OR (95% CI)#	Adjusted OR (95% CI)#	Cases (*n*=140)	Controls (*n*=140)	Crude OR (95% CI)#	Adjusted OR (95% CI)#
≤6 months	54 (39%)	48 (34%)	1.0	1.0	64 (46%)	107 (76%)	1.0	1.0	82 (59%)	57 (41%)	**2.1 (1.3–3.3)**	**2.2 (1.2–3.9)**
More than 6 months	86 (61%)	92 (66%)	**1.2 (0.7–2.0)**	**1.3 (0.8–2.3)**	76 (54%)	33 (24%)	**3.9 (2.3–6.5)**	**2.1 (1.2–3.8)**	58 (41%)	83 (59%)	1.0	1.0
Healthcare provider delay												
≤1 month	91 (65%)	65 (46%)	1.0	1.0	62 (44%)	47 (34%)	1.0	1.0	51 (36%)	28 (20%)	1.0	1.0
More than 1 month	49 (35%)	75 (54%)	**2.1 (1.3–3.5)**	**1.5 (0.8–2.8)**	78 (56%)	93 (66%)	**1.6 (0.96–2.6)**	**1.5 (0.7–3.1)**	89 (64%)	112 (80%)	**2.3 (1.3–3.9)**	**1.5 (0.7–3.0)**
First healthcare provider consulted												
Non-qualified practitioner	38 (27%)	26 (19%)	**2.0 (1.1–3.7)**	**2.0 (0.8–5.0)**	31 (22%)	32 (23%)	**1.9 (0.9–3.9)**	**2.5 (0.7–8.6)**	18 (13%)	6 (4%)	**3.9 (1.5–10.2)**	**2.9 (0.8–10.1)**
AYUSH private practitioner	4 (3%)	7 (5%)	0.8 (0.2–2.8)	0.4 (0.1–2.0)	30 (21%)	18 (13%)	**3.1 (1.4–7.0)**	**1.2 (0.4–3.9)**	12 (9%)	7 (5%)	**2.2 (0.8–5.9)**	**1.4 (0.4–4.3)**
Allopath private practitioner	49 (35%)	41 (29%)	**1.6 (0.92–2.8)**	**1.7 (0.9–3.4)**	21 (15%)	5 (4%)	**11.8 (3.9–35.7)**	**0.9 (0.4–2.2)**	28 (20%)	21 (15%)	**1.7 (0.9–3.3)**	**1.01 (0.4–2.5)**
Public health system	49 (35%)	66 (47%)	1.0	1.0	58 (41%)	85 (61%)	1.0	1.0	82 (59%)	106 (76%)	1.0	1.0

*NR: Not reported. #Crude OR/adjusted OR that is statistically significant is **emboldened, Bold value: Statistically significant odd's ratio**

Table 2: Patient delay in months

Months delayed expressed as median (interquartile range)	Delhi		Gujarat		West Bengal	
	Cases	Controls	Cases	Controls	Cases	Controls
	5 (0.7–18)	2.8 (0.6–18)	7 (2–14)	4 (1.1–6)	12 (2–24)	5 (1–24)

Wilcoxon signed rank test $P < 0.001$

Table 3: Reasons* for not seeking healthcare immediately after noticing the first symptom among the study participants (cases and controls combined) in the three states

Reasons	Delhi (%)	Gujarat (%)	West Bengal (%)
Did not know it was a disease	237 (85)	222 (79)	232 (83)
Thought it was ringworm or allergy	110 (40)	154 (55)	97 (35)
Thought it will disappear automatically	230 (82)	232 (83)	237 (85)
I did not know which healthcare provider to consult for this problem	11 (4)	137 (49)	144 (51)
I was afraid the physician will say that it was a serious disease	2 (0.7)	6 (2)	27 (10)
I had family commitments at that time	14 (5.6)	2 (0.8)	25 (9)
I did not have money to seek treatment	11 (4)	15 (5)	35 (12)

*Multiple responses

controls, though the time delay alone never contributes to the clinical multibacillary leprosy pattern, as most of the time, it is dependent on factors such as the patient's immune response and the antigenicity. Patient delay in months in three states is expressed in median (interquartile range) vide Table 2.

About 82% of the patients did not know the skin lesions as a symptom of leprosy, the majority being from Delhi (95%), and about 42% thought it to be a normal allergy or ringworm infection. About 90% thought that it would disappear automatically; about 5% in all states did not go to a physician because of fear; 5% cited family commitment and 7% of the respondents stated that they did not have money to seek treatment [Table 3].

Discussion

In this study, we found that a high proportion of cases and controls were literates and younger than 30 years in all three states. It is generally believed that the education level (literacy level) is directly proportional to that of health-seeking behaviour; however, it is quite contradictory here. Besides literacy, awareness of the disease process is equally important which could help patients in seeking early help. It is observed that only 10% of cases and about 15% of controls had a comprehensible knowledge of leprosy. Thus, about 90% of cases and controls were not aware of leprosy and could not recognise the early symptoms of skin lesions. It may reflect the reach of the 'Information, Education and Communication' component and/or its quality in the community.

The probable factors responsible for the delay in diagnosis of disease in West Bengal and Gujarat may be because of the high distribution of disease among the daily wage labourers including agricultural workers, who are relatively more common in rural areas and are illiterates.[3], The increased proportion among salaried and urban population in Delhi in contrast to the daily wage workers may be due to the fact

that Delhi, the national capital, has a large number of migrant labourers seeking better job and economic opportunities, and the disease transmission is further worsened by overcrowding in urban areas. The proportion of cases was relatively higher in the economically productive age group, also indicating negligence and wrong attitude toward health care.

The other notable factor is the distance of the primary healthcare facility. The cases and controls reported that there were some public healthcare facilities within five kilometres, but the health-seeking behaviour was toward private healthcare providers, mostly due to the increased waiting time in public facilities. It was observed that about 60% of cases first reported to private healthcare facilities including non-qualified practitioners (~20%). In a country like India, where healthcare is not solely dependent on public healthcare set up, concerted public-private efforts are a must and continuing medical education for standardisation of diagnostic skills, improvement of clinical acumen among private practitioners and centralised reporting system should be enforced. There are studies which report that even qualified dermatologist failed to recognise the signs at the earliest.[8,10]

It was found that the major contributing factors for the delay in the diagnosis of leprosy have been associated with patient-related factors. The median (interquartile range) delay in months for cases in all the three states Delhi, Gujarat, and West Bengal was five months (0.7–18), seven months (2–14) and 12 months (2–24), respectively. Furthermore, in all the three states except Gujarat, most of the cases (60%) reported a patient delay of more than six months compared to controls. All of these factors are significant and like that of other nations, where the median patient delay and healthcare delay vary between 1 month to 36 months, respectively.[11,12]

Although it is well established that multibacillary leprosy is patients' immunogenic response to the antigenicity of the pathogen, surprisingly in this study, an increased proportion of multibacillary leprosy, among the cases (with Grade 1 and Grade 2 disability), also corresponds to the time delay and is attributed to the missed opportunity for early diagnosis and prompt treatment. This is possibly due to natural history of the disease *per se*, due to which the long incubation period, insidious onset, asymptomatic painless skin lesions and chronic progressive nature of the disease all serve as reasons for the delay in seeking early help by the patient.[2] Skin lesions and the neurological manifestation of leprosy mimic others dermatological and neurological disease.[13] National Leprosy Eradication Programme should appreciate these facts, reassess and come up with innovative materials and means to improve the awareness and reduce patient delay through 'Information, Education and Communication' messages.

In India, National Leprosy Eradication Programme adopted a three-pronged strategy in August 2016: 'Leprosy Case Detection Campaign' to detect cases at an early stage from high endemic pockets in India, 'Focused Leprosy Campaign' for house-to-house survey in the village/urban area (covering 300 households) in hard-to-reach areas, and to identify Grade 2 disability in new cases. It is established again from the facts of Table 2 that the major cause of hidden cases, contributing to high Grade 2 disability rate, maybe because of low voluntary reporting as there is no awareness among people in the community. In addition to these factors, there is always fear, social stigma and discrimination of leprosy all proving to be determinantal to the National Leprosy Control Programme. In continuation of these, the 'Sparsh Leprosy Awareness Campaign' (SLAC) on 30 January 2017, was launched to promote awareness and address the issues of stigma and discrimination. Besides these, ASHA-based Surveillance for Leprosy Suspect, for finding hidden cases and contacts, will be an important step for creating awareness through 'Information, Education and Communication' and curtailing patient delay.[2]

Health and Wellness Centres, under Ayushman Bharat, a healthcare scheme likely to focus on primordial and primary prevention through upgradation of existing sub-centre and primary health centre to Health and Wellness Centres, providing comprehensive health-care services closer to home, could be the most promising solution to mitigate these patient-related factors.[14]

Limitations

The study design is a case-control one and has an inbuilt reporting bias due to the retrospective nature of data collection but the data collection was carried with caution to reduce the recall bias. As the study was carried out in three states, generalisation of the interpretation had to be cautiously executed. The matching ratio of cases and controls was 1:1 in this study, but we could not increase the controls due to operational feasibility during the conduct of the study.

Conclusion

It is evident that besides the social, economic, and demographic factors and the availability of healthcare systems, lay public should be educated about the early symptoms of leprosy and the importance of early medical consultation. Private general practitioners should be more alert of the diagnostic possibility and refer the patients promptly to the government hospitals for management, contact tracing and follow-up. Besides, raising patients' awareness would facilitate early consultation and potentially improve early detection of cases which, in turn, can reduce the associated disability. Leprosy Case Detection Campaign, Focused Leprosy Campaign, SLAC and ASHA-based Surveillance for Leprosy Suspects programmes have detected an increased number of new cases and Grade 2 disability cases in the year 2016 and led to the decrease in the rate of new Grade 2 disability cases and the number of new cases among children in the subsequent years: 2017 and 2018.

Declaration of patient consent

Institutional Review Board (IRB) permission obtained for the study.

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Conflicts of interest

There are no conflicts of interest.

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