Profile of Defaulters and Pattern of Treatment Default among Leprosy Patients at a Tertiary Care Hospital: A 10-Year Analysis

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Abstract

Background: The focus of leprosy control programs worldwide today is the WHO multidrug therapy which adequately cures the disease. Incomplete treatment puts not only the patient but the entire community at risk which may further jeopardize the leprosy control program. **Objective:** To study the magnitude of treatment default among leprosy patients, its trend in the last 10 years, and association with clinicodemographic variables. **Materials and Methods:** This was a retrospective study conducted at the urban leprosy center (ULC) attached to the dermatology department of a tertiary care centre. Data were obtained from the standard leprosy cards maintained at ULC from 2005–14. The following data were collected from the preformatted cards: age, gender, residence, occupation, type of leprosy, treatment, time of default, and so on and analyzed to see the association of defaulter status with sociodemographic and disease-related variables. **Results:** In a total of 743 cases, the rate of treatment default was 39.3%. The default status was found to have decreased significantly over the years from 2005–14 ($P = 0.03$). Majority of the treatment defaulters were migrants (47.9%) as compared with natives (29.7%) ($P < 0.001$). Regardless of the residential status, treatment default was more in pure neuritic (58.5%) and tuberculoid type (40.7%) as compared with others ($P < 0.001$). Smear negative cases (40.0%) were more likely to default than smear-positive cases (31.4%) ($P < 0.001$). Rate of defaulting was more among patients in the district where ULC was located than in the districts away from ULC ($P = 0.017$). **Conclusion:** Though the study period witnessed an overall decreasing trend over the 10-year period, treatment default remains a major concern in leprosy. Adherence to treatment is central to the success of leprosy control programs and therefore the factors associated with defaulting from treatment need to be addressed.

Keywords: *Defaulter, leprosy, multidrug therapy, treatment completion, World Health Organisation*

Introduction

Leprosy continues to be a public health problem in India and in many other developing nations across the world based on the current epidemiological evidence.[1] Despite achieving the elimination target (prevalence below 1 per 10,000) in 2005, new cases are continuously being detected pointing towards an ongoing transmission.[2] The dream resolution adopted by World Health Organisation (WHO) in 1991 to eliminate leprosy as a public health problem[3] and to expect fewer and fewer cases over the course of time is challenged by the ongoing transmission of leprosy. India leads the global leprosy load with over 50% (0.127 million) of new cases reported annually from the country.[4] Fortunately, this chronic infectious disease is still curable if adequate WHO recommended multidrug therapy (MDT) is taken: MDT-MB (rifampicin 600 mg and clofazimine 300 mg monthly supervised while dapsone 100 mg and clofazimine 50 mg daily) for 1 year [Figure 1a and b] and MDT-PB (Rifampicin 600 mg monthly supervised and dapsone 100 mg daily) for 6 months [Figure 1c and d]. The MDT a polychemotherapeutic regimen introduced by the WHO in 1982 has proven to be the best available option to combat leprosy and has undeniably been the cornerstone in achieving the WHO's elimination target. To this date, it continues to be the key component of leprosy control strategy in the absence of any vaccine.[5,6]

In India, the treatment of leprosy is provided free of cost through public hospitals. In the second phase of the National Leprosy Eradication Programme (NLEP), leprosy services were integrated with the general

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health services for better coverage and also to reduce the stigma associated with the disease.[7] Despite this, treatment default is a known problem in the leprosy control program. Although, only about 5.5% of leprosy patients defaulted in 2016–17, even a small percentage of default could have significant implications, given the population of the country.[2] In leprosy, defaulter refers to a patient who fails to complete the treatment, either by failing to take the drugs regularly or by not attending treatment centres.[8] Defaulting from treatment also results in subtherapeutic dosing, which may lead to the emergence of drug resistance and treatment failure, which compromise the control program.[9,10] Many factors could lead to treatment default. There is a paucity of studies conducted on treatment default and its associated factors in the past few years from India.

Therefore, this study was conducted with the objective to determine the magnitude of treatment default among leprosy patients, its trend over the last 10 years, and its association with clinicodemographic variables at a tertiary care centre.

Materials and Methods

Study design

This was a retrospective study conducted over a period of 10 years at the urban leprosy centre (ULC) of the department of dermatology at a tertiary care hospital in northern India.

Data collection

The study population included all the leprosy cases who had attended ULC from April 2005 to March 2015. The source of data was preformatted standard leprosy cards of the urban leprosy centre. Clinicodemographic data, treatment completion, and time of default were collected. Based on residential status, patients were categorized as natives (domicile) of J and K state and migrants from outside the state/country. The ULC was in Jammu district and patients were divided into two groups: (1) near ULC: patients from within Jammu district where ULC was located and (2) away from ULC: patients from other districts attending the ULC. Patients were grouped into four broad categories based on the type of leprosy: (1) pure neuritic (2) tuberculoid (tuberculoid and borderline tuberculoid leprosy) (3) lepromatous (borderline lepromatous, lepromatous leprosy, and histoid leprosy) and (4) mid-borderline.

Figure 1: Treatment response to WHO MDT. (a and b) Lepromatous patient before treatment and after 1 year of MDT-MB. (c and d) Tuberculoid patient before treatment and after 6 months of MDT-PB

Data management and statistical analysis

The data was entered and managed in SPSS-20 (Statistical Package for Social sciences; SPSS Inc., Chicago, IL, USA) for statistical analysis. The qualitative variables were measured as percentages/proportions and χ^2 test was applied to find statistical significance. The quantitative variables were measured as mean ± standard deviation and *t*-test were applied to find statistical significance. $P < 0.05$ was considered statistically significant.

Ethics

The study was approved by the Institutional Ethics Committee.

Results

During the 10-year period from 2005–14, the urban leprosy center registered a total of 768 patients for treatment. Data were missing for 25 patients, who were further excluded from the analysis. Out of 743 cases, 292 (39.3%) defaulted and 451 (60.7%) were declared as released from the treatment (RFT). The default status has decreased significantly over the years from 2005–2014 (χ^2 [9, n = 743] = 18.42, P = 0.03) [Figure 2]. Mean duration of disease prior to diagnosis was 15.14 ± 22.04 months among defaulters and 18 ± 27.63 months among the RFT group. Males (40.5%) were higher than females (35.1%) among dropouts, although the difference was not significant. Mean age of the patients among dropouts was 35.66 ± 15.12 years and 36.92 ± 14.78 years among the RFT group. Majority of the defaulted patients belonged to the age group 15–44 years (83.5%). In the pediatric age group

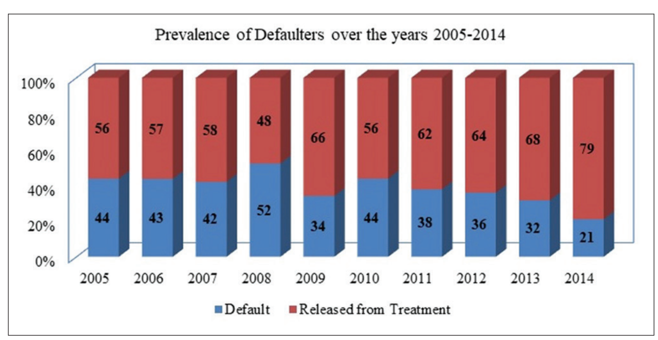

Figure 2: Trend of treatment default in leprosy cases from 2005–2014

(0–14 years), 27.3% (6/22) defaulted and 72.7% (16/22) completed the treatment (χ^2 [4, n = 743] =4.87, P = 0.30). Occupational status significantly affected the default rate (χ^2 [6, n = 743] = 41.68, P < 0.001). Among the defaulters; 49.8% (143/287) were labourers, 43.8% (21/48) armed forces, 30.3% (40/132) farmers, 35.2% (38/108) homemakers, 21.7% (20/92) service/business class, 21.1% (8/38) students, and 57.9% (22/38) others. Out of 743 leprosy cases, 390 (52.48%) were migrants and 353 (47.51%) were natives. The proportion of defaulters among migrants was 47.9% (187/390), which was significantly higher than the native population 29.7% (105/353) (χ^2 [1, n = 743] = 25.74, P < 0.001) [Table 1].

The association of default rate with the type of leprosy diagnosed is shown in Table 2. The default rate was more in patients with pure neuritic leprosy 58.5% (31/53) followed by those with tuberculoid leprosy 40.4% (109/270), followed by lepromatous leprosy 37.1% (111/299), and mid-borderline leprosy 32.1% (34/104). The difference was significant (χ^2 [2, n = 743] = 10.81, P = 0.013). The clinical type of leprosy was not mentioned in 17 (2.28%) cards. Among smear positive cases, 31.4% (69/220) were defaulters and among smear negative cases 40% (195/488) were defaulters (χ^2 [2, n = 743] = 30.20, P < 0.001). Bacteriological status was not available for 4.71% (35/743) patients. Mean time of default was 4.05 ± 2.71 months. The default rate was higher among multibacillary (MB) cases 40.7% (255/627) as compared to paucibacillary (PB) cases 31.9% (37/116) (χ^2 [1, n = 743] = 3.16, P = 0.08). The mean time of default in MB cases was 4.23 ± 2.82 months and 2.81 ± 1.27 months in PB cases (t [99.1] = 5.21; P < 0.001). Patients with single nerve involvement defaulted more 43.2% (54/125) than those with multiple nerve involvement 39.0% (215/551) (χ^2 [2, n = 743] = 1.51, P = 0.47). The rate of default decreased with the increasing disability from grade zero (41.2%) to grade 1 (37.8%) to grade 2 (36.2%) but the difference was not significant (χ^2 [1, n = 743] = 1.68, P = 0.194). Of the total cases, 98 (13.2%) were recorded as having deformities out of which, 38.8% (38/98) were defaulters (χ^2 [1, n = 743] = 0.013, P = 0.91).

The residential status was further analyzed for default based on the clinical type of leprosy. In native population, 60% (15/25) defaulted among pure neuritic patients, 29.9% (55/184) among lepromatous, 20.8% (10/48) among mid-borderline and 25.0% (22/88) among tuberculoid (χ^2 [3, n = 345] = 13.768, P = 0.003) were observed. In migrant population, 57.1% (16/28) defaulted among pure neuritic patients, 48.7% (56/115) among lepromatous, 47.8% (87/182) defaulted among tuberculoid, and 42.9% (24/56) among the mid-borderline group were observed. The default rate was found to be significantly more in pure neuritic leprosy among both natives and migrants (χ^2 [3, n = 726] = 10.813, P = 0.013). According to the disability grading, those with no disability (57.4%) defaulted the earliest (after the first dose) followed by grade 1 (27.8%) and grade 2 disabilities (14.8%). Table 3 shows the association of treatment default among patients with distance from ULC. The defaulter rate was high

Table 1: Association of treatment default with sociodemographic characteristics (n=743)

Sociocultural characteristics	Treatment status: Defaulter n=292	%	Released from treatment n=451	%	Statistical test results
Mean Age	35.66±15.12		36.92±14.78		t (741) = −1.12, P=0.26
Age Group					
0–14	6	27.3	16	72.7	χ^2 (4, n=743) = 4.87, P=0.30
15–29	108	42.4	147	57.6	
30–44	99	41.1	142	58.9	
45–59	49	33.3	98	66.7	
≥ 60	30	38.5	48	61.5	
Sex					
Male	233	40.5	342	59.5	χ^2 (4, n=743) = 1.59, P=0.21
Female	59	35.1	109	64.9	
Occupation					
Laborers	143	49.8	144	50.2	χ^2 (6, n=743) = 41.68, P<0.001
Farmers	40	30.3	92	69.7	
Armed forces	21	43.8	27	56.3	
Service/business	20	21.7	72	78.3	
Student	8	21.1	30	78.9	
Homemakers	38	35.2	70	64.8	
Others	22	57.9	16	42.1	
Residential Status					
Natives	105	29.7	248	70.3	χ^2 (1, n=743) = 25.74, P<0.001
Migrants	187	47.9	203	52.1	

Table 2: Association of treatment default with disease-related variables (n=743)

Clinical variable	Treatment status				Statistical test results
	Defaulter		Released from treatment		
	n	%	n	%	
Type of leprosy					
Pure Neuritic	31	58.5	22	41.5	χ^2 (2, n=726*) = 10.81, P=0.013
Lepromatous (LL+H + BL)	111	37.1	188	62.9	
Mid Borderline (BB)	34	32.7	70	67.3	
Tuberculoid (BT+TT)	109	40.4	161	59.6	
Smear Results					
Positive	69	31.4	151	68.6	χ^2 (2, n=708#) = 30.20, P<0.001
Negative	195	40.0	293	60.0	
Mean duration of Disease	15.14±22.04		17.18±27.63		t (741) = −1.06, P=0.29
Duration of Disease					
<6 months	141	40.1	211	59.9	χ^2 (3, n=743) = 2.20, P=0.53
7–12 months	64	37.0	109	63.0	
13–24 months	47	44.3	59	55.7	
> 24 months	40	35.7	72	64.3	
MDT type					
PB	37	31.9	79	68.1	χ^2 (1, n=743) = 3.16, P=0.08
MB	255	40.7	372	59.3	
Nerve involvement					
None	23	34.3	44	65.7	χ^2 (2, n=743) = 1.51, P=0.47
Single	54	43.2	71	56.8	
Multiple	215	39.0	336	61.0	
Disability grade					
0	162	41.2	231	58.8	χ^2 (1, n=743) = 1.68, P=0.194
1	76	37.8	125	62.2	
2	54	36.2	95	63.8	
Deformity					
Present	38	38.8	60	61.2	χ^2 (1, n=743) = 0.013, P=0.91
Absent	254	39.4	391	60.6	

LL=Lepromatous, H=Histoid, BL=Borderline lepromatous, BB=Mid-borderline, BT=Borderline tuberculoid, TT=Tuberculoid, MDT=Multidrug therapy, PB=Paucibacillary, MB=Multibacillary. *Type of leprosy not mentioned in 17 patients #Smear results not available in 35 patients

Table 3: Association of treatment default with distance from ULC

Distance from ULC#	Treatment status				Total
	Defaulter		RFT		
	N	%	n	%	
Near ULC	185	42.9	246	57.1	431
Away from ULC	107	34.3	205	65.7	312
Total	292	39.3	451	60.7	743
Statistical Test Results	χ^2 (1, n=743) = 5.649, P=0.017				

ULC=Urban leprosy centre, RFT=Released from treatment. #ULC located in Jammu district

among patients living/residing near ULC as compared to patients visiting ULC from other districts and this was statistically significant (χ^2 [1, n = 743] = 5.649, P = 0.017).

Discussion

Leprosy control has witnessed impressive strides over the years, from the days of local solutions such as chaulmoogra oil to dapsone monotherapy, and further to WHO MDT which has led to the elimination of leprosy in most parts of the world.[11] This study was conducted with the objective of determining the rate of treatment default, its trends, and association with clinicodemographic variables.

In our study, the rate of treatment default was 39.3% which is much higher than reported by Kumar *et al*. (27.11%) in their study which was based on data collected in active surveys in Agra district during 2001 to 2010.[12] However, in a study by Raju *et al.* conducted over a period of 4 years from 2007 to 2010 in four leprosy treatment centers across four states viz. Uttar Pradesh, Chhattisgarh, Maharashtra, and Andhra Pradesh; the default rate reported was as high as 54.3%.[13] In the present study, the default rate has, however, shown an overall decreasing trend over the years. Male patients defaulted more as compared to the female patients which is similar to the observations made by Raju *et al.*[13] but contrary to the findings of Kumar *et al.*[12] The results of our study showed that most of the defaulters were migrants (47.9%) from other states and a few from Nepal. This may be due to the poorer approachability and obstacles faced in regular accessibility of healthcare system by the migrants and may further be attributed to language differences between caregivers and migrants, leading to inappropriate information/motivation for treatment completion. The occupation of the patients was also seen to significantly influence the treatment completion rate. Labourers (49.8%) defaulted more as compared to other occupations. Loss of daily wages and constant mobility in search of work may be the possible reason for drop out in such patients. Defence personnel also contributed to a significant percentage of default cases (43.8%). This is also a mobile group with frequent change of posting between different states and districts within the state, which could lead to a higher default rate. Other more stable population groups such as homemakers, farmers, businessmen, and students contributed 35.2%, 30.3%, 21.7% and 21.1% to the default rate, respectively.

A significant association was found between treatment default and type of leprosy. Patients with a pure neuritic type of leprosy defaulted the most (58.5%). The absence of noticeable skin lesions could be linked to the higher default rate in pure neuritic leprosy. Lepromatous and mid-borderline patients and those with grade 2 disability had a better treatment completion rate than those with less severe types and with no disability or with grade 1 disability, respectively. The obvious and visible nature of deformities may be the reason for their adherence to the treatment. Raju *et al.*[13] however, reported the variable association of default rate with disability grade at the four centres in their study. While in one centre, the default rate was significantly higher among patients with grade 2 disability as compared with grade 0/1 disability, in another centre opposite association was found. The varied influence of disability grade on MDT compliance in different centers was attributed to local cultural factors.[13] Among our study population, migrants (48.7%) in the lepromatous group defaulted more as compared to natives (29.9%). The higher bacillary load and infectivity of defaulted lepromatous patients (LL, Histoid and BL) not only results in the progression of their own disease and disability but also makes them a source of infection to others.[14] Patients on the 6-month long PB regimen defaulted less compared to patients on the 12-month long MB regimen (31.9% vs 40.7%) and this might be due to the shorter duration of PB treatment and hence better compliance. Similar observation was made by Raju *et al*.[13] However, in a study conducted in Uttar Pradesh by Kumar *et al.*[12], the default rates were observed to be high with standard WHO-MDT treatment both for PB and MB leprosy as compared to ROM (rifampicin 600 mg, ofloxacin 400 mg, and minocycline 100 mg taken monthly for 6 months in PB cases and 12 months in MB cases) treatment. Smear positive patients defaulted significantly less (31.4%) than the smear-negative patients (40%), presumably due to less severe disease in the latter. Moreover, those with multiple nerve involvement defaulted less as compared with single nerve involvement (39% vs 43.2%).

Distance from the ULC was found to have a significant influence on treatment default rate. Patients near ULC (431/743;58%) showed a significantly higher default rate (185/431;42.9%) as compared to patients away from ULC (107/312;34.3%) (P = 0.017). The possible reason could be that the majority of population near ULC was of migrants (314/431; 72.9%) and also among the dropouts near ULC (185/592; 63.4%), the majority (147/185; 79.5%) were migrants as compared to dropouts away from ULC (P < 0.001). This is contrary to the study by Rao *et al.*[8] who reported a higher default rate in patients from outside the district. Another reason could be the higher percentage of laborers near ULC (217/431;50.3%) of which majority were again dropouts as compared to away from ULC.

Conclusion

The present study found an overall decreasing trend of default but the default rate is still high and cannot be ignored. The default rate was found to have a significant association with the type of leprosy, occupation and residential status. Treatment default leads to disease progression, continued transmission, and promotes the development of resistance. The causes leading to treatment default can be diverse and need to be further studied and addressed for better patient compliance and success of the control program. The major limitation of our study was that the exact reason for default among the study population could not be ascertained due to the retrospective study design. We suggest further research into the causes of default using questionnaires in patients who return to the treatment center after default. This would help in addressing the cause and in appropriate counselling of the patients to decrease the default rate.

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Conflicts of interest

There are no conflicts of interest.

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