Leprosy Patients Attending the Out Patient's Clinic at Agra:
A Retrospective Analysis of the Characteristics and Frequency of Regularity VS Irregularity for Determining Absenteeism, Non-adherence and Non-compliance

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Abstract: This study reports a retrospective analysis of the records of 2709 leprosy patients, attending the Out patient's Clinic at Agra, over a 1-year period, 2005. The patients with leprosy have been categorized into three groups, viz., regular, irregular and the drop-outs. The number of drop-out patients was significantly higher [Z=2.16, p=0.05] among males, 32.14% (667) when compared with females, 26.50% (168). Religion was not observed to be a significant determinant in the regularity, irregularity and/or drop-out among the patients but the locality/residential background seemed to play a key role in Clinic attendance. Patients from urban areas were less regular 38.9% (218) and the number of irregulars and drop-outs were more, i.e., 24.1% (135) and 37% (207), respectively when compared with the patients from rural areas [X^2 =14.894, p=0.00006]. Pauci-bacillary or multi-bacillary type of leprosy did not appear to be a significant determinant in the regularity, irregularity and / or drop-out among the patients. With regard to the various professions, the number of irregulars and drop-outs among patients engaged in some kind of business seemed to be more. The patients in whom the disease had become inactive, 69.7% (60) seemed to be more regular in clinic attendance than the patients with active leprosy disease. The irregularity and drop-out rate was significantly less [X^2=5.107, p=0.078]. In all, 1226 (45.26%) patients were found to be regular in clinic attendance but 648 (23.92%) patients were irregular and 835(30.83%) patients were dropouts. The present study looked at the characteristics and factors responsible for irregular attendance of a large number of patients over a 1-year period, even after 50 years of implementation of the Leprosy Control/elimination programmes. This study is the first of its kind in Northern India.

Key words: Leprosy patients, OPD attendance, irregularity, non-adherence, non-compliance

INTRODUCTION

India has the largest number of known cases of leprosy and northern region incidentally happens to be endemic for the disease. WHO lists leprosy as one of the major health problems of developing countries including India, Brazil, Africa, Nepal and Bangladesh[1-3]. Leprosy is a chronic disease associated with deformity in some cases, which has given rise to the social stigma and ostracizing of patient from society. The Government of India launched the National Leprosy Elimination Program (NLEP) in 1952-54 with the aims of eliminating leprosy through early detection of cases by population survey, contact screening/examination and voluntary referral by the year 2000 AD[4]. To achieve the goals of NLEP, it is necessary to treat all leprosy patients so that transmission of the disease can be stopped. This Institute, originally named JALMA (Japanese Leprosy Mission for Asia) was started by the Japanese people, way back in 1962 for the treatment, care, support and management of leprosy patients. It was subsequently handed over to the Government of India in 1963. This Institute caters to the needs of a large number of leprosy patients in the northern region of India. Every year, around 5,000 patients attend the Out patient's Clinic. The patients are given free treatment after diagnosis of the disease, monitored and followed-up carefully. In order to help the patients and reduce the burden of travel and expenses, they are even provided 75% concessional pass to travel by Railways. Physiotherapy and surgery are also provided to complicated cases.

In the present study, a retrospective analysis of the records of 2709 leprosy patients, attending the Unit-1 of

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Out patient's Clinic at Agra, over a 1-year period, 2005 were carried out to study the characteristics and factors responsible for absenteeism, non-adherence and non-compliance. This would provide an insight into the actual situation in this region of the country even after 50 years of the implementation of NLEP.

MATERIALS AND METHODS

Study design: In the present study, data was collected from the record files of the Unit-1 of the Out patient's Clinic (OPD) of National JALMA Institute for Leprosy & other Mycobacterial Diseases, Agra over a 1-year period, 2005 and analysed for regularity, irregularity and drop-out rates among the leprosy patients.

Inclusion criteria: A total of 2709 patients were included in the study. The Clinicians made the diagnosis of active leprosy disease based on the signs, symptoms, clinical and bacteriological findings. The socio-demographic data namely, age, gender, residential background (rural vs urban), occupation/profession, religion, type of disease, status of initial infection/disease and history of earlier treatment etc., were recorded. Leprosy patients came from rural and urban areas from different districts of Uttar Pradesh like (Barielly, Chandosi, Farrukhabad, Haldwani, Hathras, Kannauj, Moradabad, Pilibhit, Shahjahanpur, etc.) and adjoining states namely Madhya Pradesh (Badayun) and Rajasthan (Dholpur) in Northern India. The leprosy cases in the study were under surveillance after being treated with a full course of standard anti-leprosy multi-drug therapy, for varying periods ranging between 12-24 months. The patients were classified as tuberculoid (TT), borderline-tuberculoid (BT), mid-borderline (BB), borderline-lepromatous (BL), lepromatous (LL) and neuritic (N) leprosy according to Ridley-Jopling criteria[5]. Further, TT, BT and N leprosy patients were classified as pauci-bacillary whereas BB, BL and LL were the multi-bacillary type of patients. The regularity of treatment was termed according to their attendance at the OPD (as defined by NLEP/NLCP), i.e., Regular-4 weeks or over 75% of attendance; Regular, fairly-25-39 weeks or 46-74% of regular attendance; Irregular-10-24% weeks or 20-45% of regular attendance; Practically nil-below 10 weeks, or below 20% attendance; Discontinue-nil attendance[6]. In our study, patients who took total treatment for 9 to 12 months were considered as the regular patients and those who did not complete 9 months of treatment as the irregular patients. The drop-outs were those who visited the Out Patient's Clinic once only.

Statistical analysis: The data were statistically analyzed by the Chi-Square test and normal t-test was applied to test the equality of proportion.

RESULTS

Table 1 shows the socio-demographic characteristics, i.e., sex, religion, residential background, (rural vs urban), occupation/profession, type of disease, status of initial infection/disease and history of earlier treatment of all the 2709 patients. Out of the 2709 patients attending the OPD, 76.5% (2075) were males whereas 23.4% (634) were females. 74.4% (2016) were hindus and 25.5% (693) were muslims. 96.8% (2623) of the leprosy patients had active disease at the time of inclusion in this study. 62.5% (1693) had pauci-bacillary and 37.5% (1016) had multi-bacillary types of leprosy. 57.5% (1560) were treated and 42.4% (1149) were not taking any treatment at the time of inclusion in the study. Among the male patients, 44.7% (931) were regular but irregularity was observed among 23% (477) and drop-outs among 32.1% (667). Among the female patients, 46.5% (295) were regular but the number of irregular (171) and drop-out (168) patients was almost equal, i.e., 26% in each category. The number of drop-out patients was significantly higher [Z=2.16, p=0.05] among males, 32.14% (667) when compared with females, 26.50% (168). Religion was not observed to be a significant determinant in the regularity, irregularity and / or drop-out among the patients. The locality/ residential background seemed to play a key role in Clinic attendance. Patients from urban areas were less regular 38.9% (218) and the number of irregulars and drop-outs were more, i.e., 24.1% (135) and 37% (207), respectively when compared with the patients from rural areas. This was statistically a significant determinant in the clinic attendance [$X^2 =14.894$, p=0.00006]. Pauci-bacillary or multi-bacillary type of leprosy did not appear to be a significant determinant in the regularity, irregularity and / or drop-out among the patients. With regard to the various professions, the number of irregulars and drop-outs among patients engaged in some kind of business seemed to be more, i.e., 31.6% (12) and 34.2% (13), respectively. When compared patients with other occupations and even among housewives, the rate of irregularity and drop-outs among businessmen was significantly less [$X^2=21.06$, p=0.015]. Among the patients with active leprosy disease, 44.4% (1166) were regular, 24.3% (639) were irregular but 31.1% (818) were drop-outs. This is a matter of serious concern since these patients serve not only as a reservoir for further transmission of the infection but would also

Table 1:   The socio-demographic characteristics of the leprosy patients attending the Oupatient's clinic at Agra

Parameters		Patients [Numbers (%)]				Statistics X^2(p value)
		Regular	Irregular	Drop-outs	Total	
Sex	Male	931 (44.77%)	477 (22.99%)	667 32.14%)	2075	X^2 = 8.541 (p = 0.014)
	Female	295 (46.53%)	171 (26.97%)	168 26.50%)	634	
Religion	Hindu	900 (44.6%)	490 (24.3%)	626 (31.1%)	2016	X^2=1.278 (p = 0.528)
	Muslim	326 (47.0%)	158 (22.8%)	209 (30.2%)	693	
Residential background	Rural	1008 (46.91%)	513 (23.87%)	628 (29.22%)	2149	X^2 = 14.894 (p = 0.0006)
	Urban	218 (38.93%)	135 (24.11%)	207 (36.96%)	560	
Types of profession	Agriculture	229 (43.7%)	123 (23.5%)	172 (32.8%)	524	X^2 = 21.06 (p = 0.015)
	Business	13 (34.2%)	12 (31.6%)	13 (34.2%)	38	
	Service	207 (40.4%)	125 (24.4%)	180 (35.2%)	512	
	Others	442 (48.9%)	192 (21.3%)	269 (29.8%)	903	
	Child	40 (40.8%)	25 (25.5%)	33 (33.7%)	98	
	Housewife	295 (46.5%)	171 (27.0%)	168 (26.5%)	634	
Types of disease	Pauci - bacillary	767 (45.3%)	411 (24.3%)	515 (30.4%)	1693	X^2= 0.49 (p = 0.786)
	Multi - bacillary	459 (45.2%)	237 (23.3%)	320 (31.5%)	1016	
Clinical disease/ Bacterial Index	Active	1166 (44.45%)	639 (24.36%)	818 (31.19%)	2623	X^2 = 22.035 (p = 0.00001)
	Inactive	60 (69.77%)	9 (10.47%)	17 (19.76%)	86	
Treatment status	Treated	708 (45.5%)	351 (22.5%)	501 (32.1%)	1560	X^2= 5.107 (p = 0.078)
	Untreated	518 (45.1%)	297 (25.8%)	334 (29.1%)	1149	
	Total	1226 (45.26%)	648 (23.92%)	835 (30.82%)	2709	

eventually develop complications. Among the patients in whom the disease had become inactive as evident from the bacterial index, 69.7% (60) were regular, the irregularity and drop-out rate was 10.4% (9) and 19.7% (17), respectively. This appeared to be a statistically significant determinant for clinic attendance [X^2=5.107, p=0.078]. Thus, regular clinic attendance had an impact in rendering the active state of the disease to an inactive status. In all, 1226 (45.26%) patients were found to be regular in clinic attendance but 648 (23.92%) patients were irregular and 835(30.83%) patients were dropouts.

DISCUSSION

Leprosy is a major public health problem in most of the developing world and is often found in conditions connected with poverty, overcrowding, poor sanitation and insufficient nutrition[7,8]. According to current WHO data, the current global prevalence rate is around 1.4 cases per 10,000 people. Around 5,00,000 new cases of leprosy are registered each year. India alone has about 5,00,000 infected people, which represents 63% of the global occurrences and 87% of the cases for the region[9]. Leprosy, a chronic infectious disease that, if left untreated, can cause debilitating deformities and slowly progress throughout one's life. It is characterized by peripheral nerve damage, cutaneous lesions and a wide range of clinical manifestations. In order to contract the disease, one has to live in close contact with an infected individual for a prolonged amount of time[10,11]. These physical effects paired with the social stigma of being infected with this dreaded disease, often lead to those affected being afraid to come forward to seek treatment In the early stages of

Table 2: The comparative studies and the various reasons for non-compliance of Leprosy patients by other authors

Authors	Place of study	Year of study	Total no. of Leprosy Patients	Irregular Patients (%)	Reasons for non –compliance
Bhagoliwal et al [27]	Kanpur	1979	252	79 (31.23%) - regular 174 (68.77%) – defaulter	Carelessness, illiteracy, ignorance, prolonged treatment period, social stigma, religious ceremonies, false feeling of complete recovery, failure to accept the diagnosis.
Ekambram et al [28]	Tamil Nadu	1974	-	-	rich and prominent persons of the totality are not willing to come to the public clinic. Daily labour, minimal lesions, dis-belief,dis-satisfaction, with prolonged treatment, social stigma, occasional absence due to religious functions.
Kannan et al [29]	Tamil Nadu	1992	500	289 (57.8%) - regular 211 (42.2%) – irregular	[rural patients were more regular (61.2%) than their urban counterpart (54.4%)].
Nair et al [30]	South India	1955-75	10,272	42.75%	-
Nigam et al [31]	Jhansi	1979	1970	- irregular 52% - regular	Economic reasons : 29.5%, No time to attend clinic - 12.5% Ignorance - 22.9% Social stigma - 1.2% Reaction in leprosy - 12.5%
Nwosu et al [32]	Nigeria	2002	53	39.6% - irregular 7.5% - defaulter	Attendance at meetings, work at home, fear/shame/indignation, no confidence in treatment.
Raghavia et al [33]	Tamil Nadu	1987	3382	150	irregulars : backward (54%), scheduled castes (35%), more (32%) in the initial phase of the disease, illiterate group (61%). work
Shesh Pal et al [34]	Agra	1985	195	71 (36.41/%) – irregular	Miscellaneous : extremes of season, harvest, festivals - 18.3%, Practical : long distances, family problem, poverty, illnesses - 63.4% Therapeutic : no benefit, loss of index card, no attention to other complaints - 2.8%; Lack of awareness : apathy, sympatomatic, unaware - 15.5%
Vellut et al [35]	Southern India		1200	120	Anxiety for loss of income
Present Study, Yadav et al	Agra	2005	2709	Regular - (45.26%) Irregular - 648 (23.92%) Drop-Outs - 835 (30.83%)	Irregularity and drop-out patients are more among Males, patients from urban areas and those with active disease.

the disease[12]. The emergence of drug-resistant *Mycobacterium leprae*, as well as increased numbers of cases worldwide, have led to global concern about this disease[13]. Early recognition and treatment limits damage by the disease, renders the person non-infectious and allows for a normal lifestyle[14,15]. Although years are required for the elimination of *M.leprae* from the skin, most bacilli are dead within 3-6 months of the initiation of effective therapy. The shedding of viable *M.leprae* in nasal secretions and bacteremia also cease within 3-6 months. Therefore, except for the first few months of treatment, outpatient management is adequate for the vast majority of patients[16,17]. To minimize the possibility of relapse, therapy should be continued until all *M.leprae* have disappeared from the skin, a matter of at least 5 years in

lepromatous patients[18]. However, lifelong chemotherapy is indicated in patients who fail to recover lepromin reactivity because persisting mycobacteria predispose these patients to relapse. Patients with tuberculoid leprosy should be treated for 1-2 years beyond the resolution of apparent lesions[19]. Sub-clinical disease is common in endemic areas and the infection progresses to clinical disease in only a select few. Patients with leprosy can be treated on an outpatient basis but some may need hospitalization for acute complications. Most patients first need an explanation of the diagnosis and prognosis, their fears should be addressed because of the cultural stigma associated with leprosy. They may need psychological counseling because they may have difficulty in coming to terms with the disease or in feeling rejected by

society. The management of leprosy includes chemotherapy to stop the infection, treatment to minimize potential physical deformities and physical, social and psychological rehabilitation. Potential deformities can be prevented by educating patients about how to deal with existing nerve damage and by treating any sequelae of this damage. Close follow-up is important to ensure patient compliance[20-23]. Monitoring for drug resistance and adverse reactions to medications is essential[24]. Table 2 depicts the comparative studies of irregularity among leprosy patients by several authors in India and abroad. Although these periodic studies indicated that the reasons for irregularity are different in different regions[25-35], India continues to be one of the endemic countries with new case detection rates ranging from 0.5% to 20%. New case detection rates have decreased and this could be attributed to the better control due to multi-drug therapy and decreased transmission of *M.leprae*, with new cases dominated by a long period of incubation, in the lepromatous leprosy cases[36]. There is an urgent need to perform population based surveys of leprosy prevalence in India to assess the true extent of the problem.

Our study indicated that default and irregular clinic attendance by patients with leprosy are numerically large and may compound the problems of National Leprosy Elimination programmes and thus negate the realization of the global goal of intercepting leprosy transmission. Regularity in Clinic attendance and strict adherence to treatment regimens could have a significant effect on the epidemiology of leprosy.

We, therefore, feel that supervising the treatment of patients with active leprosy disease, irrespective of the paucibacillary or multi-bacillary status, would go a long way in reducing the irregularity in clinic attendance which, in turn, would help in early detection of new cases. An early and regular treatment, if initiated, would help in further deterioration and complications resulting from anaesthesia and associated morbidity due to nerve involvement in the infection(s) as well as further transmission of the infection. There is a need, therefore, to support an approach of targetted screening, integrate leprosy testing, counseling, referral services and direct supervision of treatment into the existing system for leprosy prevention and /or treatment services.

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