

Dermlep Study Part 3: Post-RFT Events in Leprosy Patients Presenting to Dermatologists

Abstract

Introduction: Presently the leprosy program has no defined surveillance protocols for patients who complete the fixed duration multidrug therapy and are released from treatment (RFT). Hence, the information about the post-RFT events in these patients is sparse and qualitative and quantitative data regarding their health care requirements is missing. During the *DermLep* survey carried out by the Indian Association of Dermatologists, Venereologists and Leprologists (IADVL), a number of patients presented to dermatologists during the post RFT period for a variety of symptoms. This paper analyses the events in these patients during the post RFT period. **Results:** Out of a total of 3701 leprosy patients who presented to 201 dermatologists across India during the *DermLep* survey, 708 (26.2%) were in the post RFT period (488 males; 220 females). Of these, 21% were PB and 79% MB patients as per their treatment records. Majority were in the age group of 31-59 years (55.5%); however, a significant proportion of them (20.7%) were elderly (>60 years). Majority of the patients (45.5%) presented within the first year of RFT with variable symptoms; 28% were between 1-5 years, 5.5% between 5-10 years; and 11.0% presented more than 10 years after RFT. Most common presenting complaint being persistent skin lesions as perceived by patients in 21.2%, followed by neuritis in 14.5%; trophic ulcers in 13.8%; deformities in 67 (11.8%); lepra reactions in 66 (11.6%); and recurrence of original symptoms in 6.7%. **Conclusion:** The *DermLep Survey* highlights the importance of 'post RFT' patients as an important subset of leprosy patients who visit dermatologists for various health related issues. The most common complaints in this subset were active/persistent skin lesions, lepra reactions and neuritis. In these patients, who are a sub-group of 'persons affected with leprosy' the disease related issues can persist for many years post RFT. Hence, it is important to provide services in the programme to monitor and manage these complications for the prevention of impairments, disability and the related social issues.

Keywords: *DermLep* survey, grade 2 disability, lepra reactions, leprosy, post RFT period, surveillance

Introduction

In the global leprosy program, when a patient completes the required duration of standard multidrug therapy (MDT) regimens, the patient is "released from treatment" (RFT). Nonetheless, the responsibility of the health system towards the leprosy patient does not cease with the completion of MDT as the disabilities and deformities that develop during the active phase of the disease are not always reversible and the patient needs sustained care and surveillance post-RFT. Periodic surveillance of leprosy patients following RFT has three main objectives: the recognition and management of reactions occurring after MDT, differentiating reactions from relapse, and early identification of onset or progression of

existing disability to institute appropriate measures to contain and reverse it.

In 1988, the WHO expert committee recommended that paucibacillary (PB) cases should be clinically examined once a year for a minimum of 2 years and that multibacillary (MB) cases be examined both clinically and bacteriologically once a year for a minimum of 5 years.^[1] However, 6 years later, in 1994, the WHO rolled back this recommendation citing the negligible risk of relapse after completion of WHO MDT regimens; thus, it was no longer necessary to continue annual surveillance.^[2] Instead, it was suggested that at the time of RFT, patients should be taught to recognize early signs of possible relapse and reactions and report for the treatment. This recommendation is being

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followed by the Indian National Leprosy Program till today.

It has been observed that a number of post-RFT leprosy patients, both PB and MB types, continue to experience varying signs and symptoms of the disease as well as complications, including disabilities for many years, requiring medical or surgical intervention. For these reasons, a considerable number of post-RFT patients with leprosy approach either government or private healthcare facilities. The objective of this survey is to analyze the profile and types of events in post RFT patients, observed and recorded by the dermatologists during the nationwide *DermLep* survey conducted by IADV during the year 2017–18 with the premise to comprehend the need for follow up and plan methods to address the specific needs of post-RFT leprosy patients.

Materials and Methods

This study was part of the *DermLep* study, a nationwide survey carried out to estimate the number and profile of leprosy patients presenting to dermatologists in India and the leprosy services provided to them, the results and observations of which are already published.^[3,4] A predesigned questionnaire was provided to dermatologists from all over the country between August 2017 and September 2018. It had 14 questions and was administered to the 3701 leprosy patients seen in their clinics/institutes during the study period. Nationwide, a total of 201 dermatologists took part in the *DermLep* survey. Ethical approval was obtained for the study, and informed written consent was obtained from all patients. Confidentiality of all patients and participating dermatologists was maintained, and the data was used only for the purpose of this study.

Of all the leprosy patients seen during the survey, details of the post-RFT patients were tabulated separately. The age-sex distribution, classification, presenting complaints, skin smear details, lepra reactions, and grade 2 disability status of all post RFT patients were recorded and analyzed.

Results

Out of the total of 3701 leprosy patients seen in the *DermLep* survey, 708 (26.2%) were post-RFT patients. Of these, 488 (68.9%) were males and 220 (31.1%) were females. The age of the patients ranged between 10 and 93 years. Most patients (n = 356; 55.5%) belonged to the age group of 31–59 years, followed by 147 (23.2%) in the age group of 16–30 years. Further, 133 (20.7%) were elderly (>60 years), and 4 were children (0.62%) below the age of 15 years.

The time period between RFT and the patient's visit to the dermatologists is given in Table 1. Most of the patients [322 (45.5%)] presented within the first year after RFT, 185 (26.1%) between 1 and 2 years, 84 (11.9%) between 2 and 5 years, 39 (5.5%) between 5 and 10 years, and 78 (11.0%) more than 10 years after RFT. Based on

their case records, the information regarding the type of MDT taken was available for 644/708 patients. It was found that 134 (21%) patients received PB-MDT and 510 (79%) received MB-MDT.

Presenting complaints and reason for the visit to the dermatologist

The presenting symptom and reason for consulting the dermatologist were recorded for 566/708 patients [Figure 1]. Of them, the most frequent reason was active skin/persistent lesions in 120 (21.2%) and together with recurrence of symptoms in 38 (6.7%) was the most common complaint in 158 (27.9%) of the patients. Following closely were lepra reactions or neuritis in 148 (26.1%) patients and ulcers or deformity in 145 (25.6%) patients. This was followed by the “need for reassurance” about the complete regression of the disease or its infectiousness in 115 (20.3%).

Lepra reaction and grade 2 deformity (G2D) in post-RFT patients

The survey included a question on the presence of grade 2 disability (G2D). Of the 684 responses recorded in the post-RFT group, 260 patients (37.9%) had G2D. Lepra reactions were observed in 148 (21.63%) of the patients. When the presence of lepra reaction and G2D was correlated, a high proportion of G2D 105 (70.94%) was found to be present in 225 post-RFT patients with lepra reactions. This was in contrast to only 155 (28.91%) patients with G2D recorded in the 440 patients without reaction. Furthermore, analysis of 260 post-RFT patients with G2D revealed that 96 (36.9%) of them had lepra

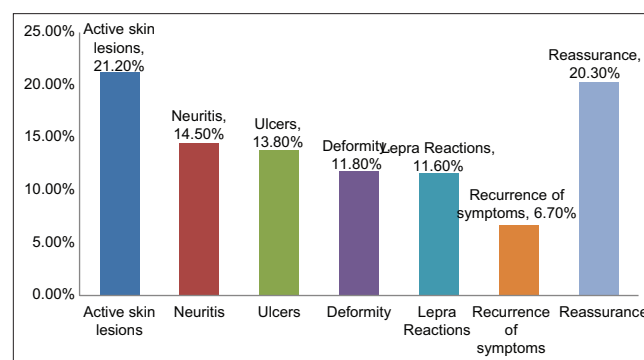


Figure 1: Presenting complaints post-RFT

Table 1: Duration of patients visit to dermatologist after RFT

Duration of visit after RFT	No. of patients (%)
<1 year	322 (45.5%)
1-2 years	185 (26.1%)
2-5 years	84 (11.9%)
5-10 years	39 (5.5%)
>10 years	78 (11.0%)
Total	708

reactions (T1R in 24 (9.2%) patients and T2R in 72 (27.7%) patients); the type of lepra reaction in a patient with neuritis could not be ascertained.

Registration of post RFT with NLEP

At the time of reporting to the dermatologist, 379 (58.5%) post-RFT patients were found to be registered with the NLEP, whereas 269 (41.5%) were not registered.

Discussion

The National Leprosy Eradication Program, India (NLEP) training manual mentions that the criteria for declaring a patient as cured/released from treatment (RFT) is the completion of 6 and 12-months doses of MDT for PB and MB patients, respectively. A leprosy patient is recorded as RFT in the program registers at the expected month of completion of treatment.^[5] It is an important task as the “number of patients RFT during a year” is one of the quality-of-service indicators of the program. Simultaneously, when patients are declared as RFT, their names are deleted from the leprosy registers to denote the “end of the treatment.”^[6]

While the patient is on MDT, the review of the “disability status” of patients initially and its follow-up is included in the operational guidelines for DPMR of 2012 by NLEP; however, the follow-up of RFT patients is not a part of the program.^[7] All the patients when being declared as RFT by health workers are to be explained that stopping chemotherapy does not mean stopping self-care by the patient. Only if the RFT patient needs treatment (e.g., for ulcers) or physiotherapy, the required services are arranged by the NLEP.^[6] With no provision for periodic follow-up of post-RFT patients, there is no reliable data on the issues faced by this important group of leprosy patients who have completed their MDT but are not entirely free of impediments caused by the disease.

The present study has attempted to record the magnitude and profile of problems faced by the post RFT patients attending dermatology clinics to highlight the need for medical attention and care even after the completion of MDT. Of the 708 post-RFT patients, 322 (45.5%) presented to dermatology clinics within the first year of RFT, whereas 507 (71.6%) presented within two years post RFT, which highlights the need for closer monitoring in immediate post-RFT years. The observation that 123 (17.4%) patients presented between 2 and 5 years after RFT and 78 (11.0%) presented more than ten years after RFT provides clear evidence that leprosy patients suffer from long-term disease complications warranting long-term care and support.

Age groups at risk of post-treatment events

The patients in this study included 4 children, but the predominant patient group was of young and middle-aged adults, who form the most productive age groups in

the society. It was also observed that a significant proportion (20.7%; n = 133) of the patients were elderly patients above the age of 60 years. Leprosy in the geriatric group has not received much attention in the past. However, with increasing life expectancy in India, we are likely to encounter more leprosy patients in this age group as highlighted by a case report^[8] and a recent study.^[9] A study published last year from Brazil found that elderly patients have a higher likelihood of MB disease and are at greater risk of developing disabilities.^[10] Given the fact that the health system puts lesser emphasis on the issues of the geriatric age group, they carry a higher risk of delay in diagnosis, treatment failure, and becoming a stagnant pool of infection in the community.

Most common presenting complaint in post-RFT patients

The predominant reason for the post RFT patients to consult dermatologists was because the leprosy skin lesions continued to be active and the recurrence of original symptoms (n = 158, 27.9%). This shows that even after the completion of MDT in over 1/4th of patients, the skin lesions may remain visible, and patients may have residual anesthesia/paresthesia, or these lesions could clinically be still active or in type 1 reaction requiring attention from a specialist healthcare provider to address their concerns. The persistence of visible skin lesions, either active or residual in post-RFT patients, can be a cause for apprehension among them that they are not completely free of the disease. Importantly, facial patches and lesions of leprosy on exposed parts of the body can lead to social stigma and discrimination, prompting patients to seek medical treatment until the complete disappearance of the lesions.^[11]

High-risk groups for post-treatment events

Patients of the entire spectrum presented with post-MDT issues, but MB leprosy patients formed 79.2% of them (510/644). MB leprosy patients can include BT and BB patients with more than 5 lesions as well as all BI positive and BL/LL patients. Some of these patients remain smear-positive at the time of RFT and are of concern both to the patients as well as to the health system. High-BI MB patients are identified as patients who are at the highest risk of relapse^[12], T1R and T2R,^[13] neuritis, and grade 2 disabilities.^[14] With the disbanding of the vertical system and the integration of leprosy into the general health services, there is no clear mechanism to follow-up such MB patients or to perform periodic skin slit smear examinations to address their needs as well as adequately manage their complications. The fact that a large number of post-RFT patients sought the help of dermatologists points to their role and contribution to the healthcare system in our country. Although skin smears have been given up in the program, they continue to be a useful tool in leprosy diagnosis and in monitoring the progress of treatment. This

study also brings out the fact that dermatologists rely on SSS for a full evaluation of their patients, with 57.23% of them using it routinely in the management of leprosy.^[4] Smears have great prognostic value in post-RFT patients in documenting the fall in BI, possible reactivation of the disease, or bacteriological relapse, as well as in alerting the physician to the possibility of drug resistance.

Leprosy patients with High BI are considered as cases of concern, and issues regarding their management, such as whether they should be treated for longer, for 24 months or until smear negativity, or with an alternate drug regimen is an important debate.^[15] Two studies of post-RFT patients carried out in India observed that a proportion of MB patients harbor viable *M leprae* even after completion of the full 12-month course of MDT.^[16,17] This finding is of epidemiological concern as although they are considered “cured” by the health system, they can continue to transmit the disease in the family and community. This debate should be resolved for the long-term benefit of the patients as well as for mitigating leprosy in the country.^[13]

Lepra reactions, neuritis, and disabilities in post-RFT patients

Lepra reactions are closely linked to neuritis as both type 1 and type 2 reactions are known risk factors for and often precede neuritis. In the present study, 82 patients (14.5%) presented to the dermatologist because of neuritis and 66 (11.6%) with lepra reactions, together adding up to 26.1%, making it the second most common presenting complaint in the post-RFT period. A study from Brazil documented that T1R occurred in 37.1% of their post-RFT patients, T2R in 18.6%, and neuritis in 13.9% of their patients.^[18]

The WHO recognizes that lepra reactions and accompanying neuritis can occur both during treatment and in the post-MDT period.^[19] In the present study, 60% (n = 393) of the patients belonged to the borderline group (BT, BB, and BL), which is known to be immunologically unstable and prone to T1R and neuritis. Further, BL and LL patients comprised 319 (48.70%) patients, of whom 68 (21.31%) were high-BI patients, all of whom are at known higher risk for T2R and neuritis.^[20]

The strong association of lepra reactions and the development of G2D is highlighted from the data. A higher proportion of those who had lepra reactions developed G2D (45.7%) than those without lepra reactions (35.2%). This points to the importance of identifying reactions and managing them effectively to prevent the development of G2D. Interestingly, a reverse analysis of the 260 patients in the study with G2D revealed that 63.1% had no reaction but still developed G2D. This suggests that in the post-RFT period, patients can insidiously develop impairments. Other studies have also documented the occurrence of late T1R, recurrent

and chronic ENL reactions, and neuritis/nerve function impairment (NFI) in the post-RFT period.^[21,22]

It is known that in long-standing treated leprosy patients, the persistent bacterial antigen can incite nerve autoantibodies that can perpetuate neuropathy.^[23] A study from Brazil observed that the impairment status worsened in 40% of patients 10 years after RFT.^[24] Studies have also shown that the cumulative probability of worsening of the physical disability grade of persons treated and declared cured of leprosy increases with time.^[25,26] It is noteworthy that multivariate analysis showed no significant difference between PB and MB cases with regard to the rate of disability progression.^[26] These observations emphasize the importance of post-RFT surveillance as a tool in the program to prevent development and worsening of disabilities. In addition, specialized tertiary centers need to be strengthened for the care of chronic ulcers, deformities, and to provide reconstructive surgery and occupational therapy as an integral part of the program as “care after cure” for post-RFT patients.

Persons affected by leprosy (PAL) are the best resource to identify their needs and problems and to set priorities to improve planning and management of leprosy services.^[27] There are recommendations globally for regional and national community-based organizations to involve PAL through meaningful engagements at all levels of decision-making processes regarding policies and programs that directly concern their lives.^[28] It is important to point out here that post-RFT individuals form a significant part of this PAL group. There are various initiatives to involve PAL as key stakeholders in addressing social issues of stigma and discrimination faced by them. However, a gap exists between their involvement in planning social remedial measures and the medical and physical challenges they face after RFT. Addressing only their social needs and ignoring their medical needs would be a disservice to this important group.

Conclusion

Although more than 16 million people affected by leprosy have received MDT^[29] and have been declared “cured,” it is estimated that 3–4 million people are living with visible impairments or deformities due to leprosy.^[29] The present study highlights the various complications or consequences that can occur in patients who have completed MDT. Some common issues were persisting skin lesions and anesthesia, lepra reactions, neuritis, deformity, and trophic ulcers, and all these need medical attention of high order.

Unfortunately, routine surveillance systems are yet to be put in place by most countries, including India, for post-treatment active monitoring of nerve damage and other disabling complications. The absence of a good “care after MDT” program for such patients will lead to “dehabilitation” and escalating stigma over time.^[28]

The WHO global leprosy document for 2021–30 also mentions “functioning post-treatment surveillance systems” as one of the key indicators of progress. It is important that this should be added to the national programs and implemented at all levels of care to ensure all leprosy patients get the required medical attention and care to overcome these post-RFT issues.

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Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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