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Post-Multidrug Therapy Recovery in South Indian Leprosy Patients: A Prospective Study of Nerve Function, Reaction Incidence, and Psychosocial Adjustment

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ABSTRACT

Background: Leprosy remains a major public health issue in endemic regions like South India, with nerve damage and psychosocial challenges persisting despite effective multidrug therapy (MDT). Early post-treatment monitoring is essential to detect nerve changes, reactions, and psychosocial adjustments impacting disability and quality of life. This study prospectively evaluated clinical progression, reaction incidence, psychosocial outcomes, self-care adherence, and preliminary oncological risks over six weeks post-MDT in 140 enrolled patients (112 completers).

Methods: In a prospective cohort from January 2024 to June 2025, 140 adults with confirmed leprosy completing WHO MDT (6 months for paucibacillary [PB]; 12 months for multibacillary [MB]) were enrolled at a South Indian center. Assessments included nerve function (Semmes-Weinstein monofilaments, motor testing), disability (WHO grading), depression (PHQ-9), stigma (EMIC), quality of life (WHOQOL-BREF), and self-care adherence at baseline and 6 weeks. Oncological screening used symptom review and biomarkers. Analyses involved paired t-tests, chi-square, Pearson's correlations, and Kaplan-Meier curves. Sample size was limited to 140 due to logistics, yielding >80% power based on pilot data.

Results: Among 112 completers, PB patients showed significant improvements in Nerve Function Score (mean change −0.30, p=0.002) and WHO Disability Score (mean change −0.23, p=0.01). Reaction incidence was 18% (higher in MB [25%] vs. PB [13%]; p=0.04), mostly within 4 weeks. Psychosocial parameters (PHQ-9, EMIC, WHOQOL-BREF) improved significantly (p<0.01). Self-care adherence was ≥80% in 71%. No confirmed cancers; 3.6% had risk signs warranting referral.

Conclusions: Early post-MDT care reveals neurological and psychosocial recovery with varying reactions, emphasizing multidisciplinary follow-up for optimal outcomes.

Keywords: *Leprosy; Hansen's disease; multidrug therapy; nerve function; leprosy reactions; psychosocial outcomes; self-care adherence; South India; prospective cohort; disability prevention..*

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1. INTRODUCTION

Leprosy, also known as Hansen's disease, remains a significant public health challenge in endemic regions, primarily due to its profound neurological consequences despite effective antimicrobial treatments. Advances in the treatment and evaluation of leprosy neuropathy have emphasized the role of multidrug therapy (MDT) in eradicating Mycobacterium leprae, yet persistent nerve damage often requires adjunctive interventions such as corticosteroids to manage inflammation and prevent further impairment [1]. The neurological impact of leprosy extends beyond peripheral nerve involvement, manifesting as sensory loss, motor deficits, and autonomic dysfunction, with management strategies focusing on early detection through neurophysiological assessments and tailored immunosuppressive therapies to mitigate long-term disabilities [2].

Prospective studies have highlighted the progression of leprosy reactions and associated nerve damage, particularly in vulnerable populations like children, where repeated episodes correlate with worsening neural function and underscore the need for vigilant monitoring post-diagnosis [3]. Beyond physical sequelae, leprosy profoundly affects psychosocial outcomes, with stigma mitigation efforts revealing that community-based interventions can improve social integration and reduce discrimination among affected individuals [4]. Systematic reviews further confirm the detrimental impact of leprosy on mental wellbeing, documenting high prevalence of depression, anxiety, and reduced quality of life, often exacerbated by visible deformities and societal exclusion [5].

Disability progression after MDT completion raises questions about the sufficiency of antimicrobial therapy alone, as cohorts demonstrate ongoing deterioration in physical function years post-discharge, necessitating comprehensive rehabilitation programs [6]. Survival analyses of leprosy patients released from treatment reinforce these concerns, showing elevated risks of cumulative disability over time, influenced by baseline impairment and reaction history [7]. Adherence to self-care and treatment regimens emerges as a critical factor, with cross-sectional evidence from endemic areas indicating that socioeconomic barriers and education levels significantly affect compliance and subsequent outcomes [8].

Additionally, historical cohort studies have explored the association between leprosy and cancer, suggesting an increased risk of malignancies, particularly in lepromatous forms, due to chronic immune dysregulation [9]. Further investigations into causes of death among leprosy patients have corroborated elevated cancer mortality rates, alongside other comorbidities, highlighting the need for long-term oncological surveillance [10]. Randomized trials have evaluated the effectiveness of extended versus standard prednisolone durations in addressing nerve function impairment, finding that shorter regimens may suffice for many patients while minimizing side effects [11]. Qualitative insights into factors affecting treatment adherence reveal themes such as stigma, access to care, and patient education as pivotal influencers, advocating for holistic support systems to enhance compliance [12].

Despite these advancements, gaps persist in understanding short-term outcomes immediately following MDT completion, a critical window where reactions, residual impairments, and psychosocial adjustments may manifest or worsen, potentially leading to irreversible disabilities if unaddressed. Existing literature predominantly focuses on long-term cohorts or specific complications, with limited prospective data on integrated clinical, psychosocial, and adherence metrics in the acute post-treatment phase. This underscores the need for targeted studies to inform early intervention strategies and optimize patient trajectories in resource-limited settings.

The purpose of this study was to prospectively evaluate clinical progression, leprosy reactions, psychosocial outcomes, adherence to self-care, and preliminary oncological risks in a cohort of leprosy patients over 6 weeks post-MDT, aiming to identify variability in outcomes and inform integrated post-treatment care protocols.

2. METHODOLOGY

Study Design and Setting

This prospective cohort study was conducted at a specialized leprosy treatment center situated in an endemic region. The study was carried out in collaboration with the NGO Far Corners India International, which provided essential support in patient recruitment, follow-up coordination, and community engagement, facilitating effective data collection and participant retention. The aim was to evaluate post-treatment outcomes in leprosy patients over a six-week period.

Study Population and Period

Adults aged 18 years and above, diagnosed with leprosy confirmed through clinical, bacteriological, and histopathological

criteria, were eligible. All participants had completed the WHO-recommended multidrug therapy (MDT)—six months for paucibacillary (PB) and twelve months for multibacillary (MB) cases. The study period for patient enrollment and follow-up data collection spanned from January 2024 to June 2025, with each enrolled patient completing a 6-week post-MDT follow-up.

Sample Size

The sample size was calculated using the formula:

$n=z^2\times p\times q/d^2$

where z=1.96 (for 95% confidence), p=0.45 (estimated prevalence of baseline nerve impairment), q=1−p=0.55, and d=0.07 (absolute precision).

Calculation:

$n=1.96^2\times 0.45\times 0.55/0.07^2=3.8416\times 0.2475/0.0049\approx 194$

Accounting for logistical constraints, 140 participants were enrolled, providing sufficient power (>80%) for primary outcomes based on anticipated effect sizes from pilot data.

Sampling Technique

Consecutive sampling was employed, enrolling all eligible patients presenting upon MDT completion.

Assessments and Instruments

- Clinical Assessments:

Sensory nerve function was assessed bilaterally using Semmes-Weinstein monofilaments ranging from 0.2 g to 300 g. Sensory impairment was scored on a 0−4 scale for the affected nerves (bilateral ulnar, median, and posterior tibial): 0 indicated normal sensation (ability to perceive the 2 g monofilament on palmar sites or 10 g on plantar sites); and 4 indicated severe sensory loss (inability to perceive the 300 g monofilament).

Motor function was evaluated using a modified Medical Research Council (MRC) scale (power 0−5), which was transformed to a 0−4 impairment scale for the purpose of the Nerve Function Score (NFS) calculation. On this transformed scale: 0 indicated normal strength (MRC grade 5) and 4 indicated paralysis (MRC grade 0-1).

An overall Nerve Function Score (NFS), ranging from 0 (no impairment) to 4 (severe impairment), was derived by averaging the 0−4 sensory impairment scores and the 0−4 motor impairment scores across the six key sites (bilateral ulnar, median, and posterior tibial nerves). Disability was graded on the WHO 0−3 scale.

- Psychosocial Measures:

Depression was measured using the Patient Health Questionnaire-9 (PHQ-9). Stigma was evaluated via the Explanatory Model Interview Catalogue (EMIC) stigma scale. Quality of life was assessed using the WHO Quality of Life-BREF (WHOQOL-BREF), transformed to a 0–100 scale.

- Adherence Monitoring:

Patients self-reported adherence to skin care and rehabilitation protocols through weekly diaries, with ≥80% compliance classified as high adherence.

- Oncological Screening:

Symptom history, physical examination for chronic skin lesions, and laboratory markers (CBC, ESR, CRP) were used to screen for potential cancer risks as an exploratory measure.

Inclusion and Exclusion Criteria

Inclusion criteria included adults ≥18 years with confirmed leprosy who had completed WHO MDT regimens and had no active leprosy reactions at enrollment. Exclusion criteria were the presence of immunosuppressive disorders, active systemic infections like tuberculosis, or inability/unwillingness to attend follow-ups.

Ethical Considerations

The study received approval from the Institutional Ethics Committee of Katuri Medical College and Hospital and adhered to the Helsinki Declaration. Confidentiality, voluntary participation, and patient safety were ensured throughout.

Study Procedures

Baseline assessments were conducted at MDT completion, with follow-up after six weeks. Nerve function, disability, and leprosy reactions were monitored clinically; reactions were treated following protocols using corticosteroid tapering regimens. Psychosocial questionnaires were administered at both visits, and adherence data were collected from patient

diaries. Patients exhibiting suspicious oncological signs were referred for specialized care. Data collectors were trained clinicians, blinded to baseline data for psychosocial assessments to minimize bias.

Data Analysis

Data management and analysis were performed using Microsoft Excel and IBM SPSS version 27. Continuous variables are presented as means ± standard deviations. Paired t-tests compared baseline and follow-up measures with 95% confidence intervals. Categorical data were analyzed using chi-square tests. Subgroup comparisons (PB versus MB and nerve impairment status) employed independent t-tests or chi-square tests. Associations between adherence and outcomes were examined with Pearson's correlation coefficient. Attrition bias was assessed by comparing baseline characteristics of participants who completed follow-up versus those lost to follow-up. Statistical significance was set at $p < 0.05$.

3. RESULTS

Participant Characteristics

A total of 140 patients were enrolled at MDT completion, with 112 (80%) completing the 6-week follow-up. Attrition was due to loss to contact (15%) or voluntary withdrawal (5%). No significant baseline differences were observed between completers and dropouts in age ($t(138) = 0.72$, $p = 0.47$), sex ($\chi^2(1) = 0.15$, $p = 0.70$), leprosy type ($\chi^2(1) = 0.22$, $p = 0.64$), baseline Nerve Function Score ($t(138) = 0.85$, $p = 0.40$), baseline WHO disability score ($t(138) = 0.61$, $p = 0.54$), and baseline PHQ-9 score ($t(138) = 0.93$, $p = 0.35$), though a non-significant trend toward higher dropout in rural patients was noted ($p=0.08$). The mean age of completers was 41.8 ± 13.2 years, and 62% were male. Sociodemographically, 75% resided in rural areas, 52% had primary education or less, 68% were employed in manual labor or agriculture, and 80% belonged to low socioeconomic status (Modified Kuppuswamy scale class IV-V). Paucibacillary (PB) cases accounted for 58% of the cohort, while multibacillary (MB) cases comprised 42%. Baseline nerve impairment was present in 45% of patients, with a higher prevalence in MB (60%) compared to PB (35%; $\chi^2(1) = 5.42$, $p = 0.02$).

Clinical Progression

Overall, modest improvements were observed in nerve function scores from baseline (mean 2.12 ± 0.85) to 6 weeks (mean 1.82 ± 0.95), yielding a mean difference of -0.30 (95% CI -0.45 to -0.15; $p = 0.002$, paired t-test). Subgroup analysis indicated significant improvements primarily in PB patients ($p = 0.01$), whereas no notable change occurred in MB patients ($p = 0.18$). Similarly, WHO disability scores declined from 1.38 ± 0.55 at baseline to 1.15 ± 0.72 at 6 weeks (mean difference -0.23, 95% CI -0.38 to -0.08; $p = 0.01$), with more substantial reductions in PB ($p = 0.005$) than MB subgroups ($p = 0.12$). However, variability was evident, as 25% of patients exhibited no change or minor worsening, frequently associated with pre-existing impairment at baseline (Table 1, Figure 1).

Table 1: Clinical Outcomes at Baseline and 6 Weeks Post-MDT Completion

Parameter	Baseline Mean ± SD	Week 6 Mean ± SD	Mean Difference (95% CI)	p-Value (paired t-test)
Nerve Function Score (0–4)	2.12 ± 0.85	1.82 ± 0.95	-0.30 (-0.45 to -0.15)	0.002
WHO Disability Score (0–3)	1.38 ± 0.55	1.15 ± 0.72	-0.23 (-0.38 to -0.08)	0.01

This table presents the changes in nerve function and WHO disability scores from baseline (MDT completion) to 6 weeks post-treatment in 112 leprosy patients. Nerve Function Score (0–4) is the average of sensory (Semmes-Weinstein monofilament testing) and motor (adapted voluntary muscle testing) impairment scores across bilateral ulnar, median, and posterior tibial nerves, where 0 = no impairment and 4 = severe impairment. WHO Disability Score (0–3) quantifies physical impairments per WHO grading criteria. Mean differences, 95% confidence intervals (CI), and p-values from paired t-tests are reported.

Notes:

Data presented as mean ± standard deviation (SD).

p-values indicate statistical significance of change from baseline to week 6 using paired t-test.

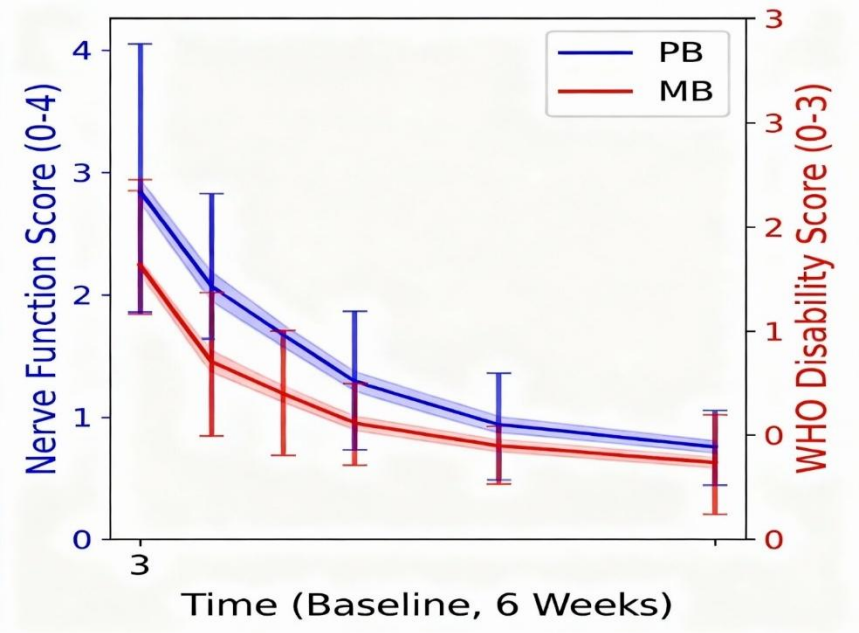

Figure 1: Trends in Nerve Function and WHO Disability Scores Over Time by Leprosy Type

This line graph illustrates the temporal trends in Nerve Function Score (0–4 scale, where 0 = no impairment and 4 = severe impairment) and WHO Disability Score (0–3 scale) from baseline (multidrug therapy [MDT] completion) to 6 weeks post-treatment in 112 leprosy patients. The Nerve Function Score represents the average of sensory (assessed via Semmes-Weinstein monofilaments) and motor (assessed via adapted voluntary muscle testing) impairment scores across bilateral ulnar, median, and posterior tibial nerves. Separate lines represent paucibacillary (PB, n=65) and multibacillary (MB, n=47) subgroups, with error bars indicating standard deviations to reflect variability. The graph highlights greater improvements in PB patients compared to MB patients, with the latter showing minimal change, particularly in nerve function.

Leprosy Reactions and Relapse

The cumulative incidence of reactions or relapse within 6 weeks was 18% (20/112), with 70% of events occurring in the first 4 weeks. Incidence was higher in MB (25%) than PB patients (13%; $\chi^2(1) = 4.20$, $p = 0.04$). All reactions were treated with corticosteroids, and 10% (2/20) resulted in minor new disabilities such as transient sensory loss. No confirmed relapses were identified, aligning with expected low short-term rates (Figure 2).

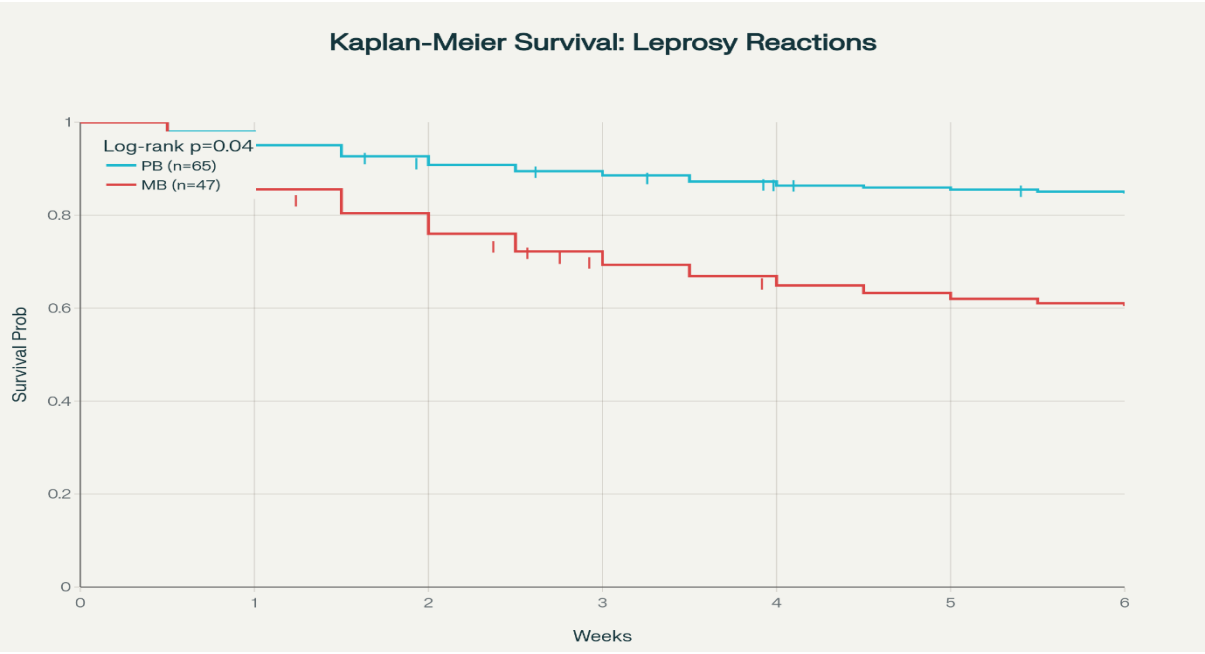

Figure 2: Kaplan-Meier Survival Curve for Time-to-Reaction Onset by Leprosy Type

This Kaplan-Meier survival curve illustrates the time-to-first leprosy reaction (or relapse) within 6 weeks post-MDT completion in 112 leprosy patients, stratified by leprosy type (paucibacillary [PB, n=65] vs. multibacillary [MB, n=47]). The x-axis represents time in weeks (0 to 6), and the y-axis represents the proportion of patients without a reaction. Separate curves for PB and MB subgroups highlight a higher incidence and earlier onset of reactions in MB patients (25% incidence) compared to PB patients (13% incidence). The graph includes tick marks indicating censored cases (patients without reactions by week 6) and a log-rank test p-value (p=0.04) to confirm the statistical significance of the difference between subgroups.

Psychosocial Outcomes

Depression scores on the PHQ-9 decreased modestly from 9.2 ± 3.1 at baseline to 7.8 ± 3.4 at 6 weeks (mean difference -1.4, 95% CI -2.0 to -0.8; p = 0.003). Stigma scores via the EMIC scale reduced from 17.5 ± 5.4 to 14.8 ± 5.9 (mean difference -2.7, 95% CI -3.6 to -1.8; p = 0.005). Quality of life, assessed by WHOQOL-BREF, improved from 58.4 ± 11.2 to 64.7 ± 13.0 (mean difference 6.3, 95% CI 4.2 to 8.4; p = 0.004). Improvements varied, with 30% of patients demonstrating minimal or no change, especially those with elevated baseline stigma (Table 2, Figure 3).

Table 2: Psychosocial Outcomes at Baseline and 6 Weeks Post-MDT Completion

Table 2: Psychosocial Outcomes at Baseline and 6 Weeks Post-MDT Completion This table summarizes changes in psychosocial measures from baseline (MDT completion) to 6 weeks post-treatment in 112 leprosy patients. Depression was assessed using the Patient Health Questionnaire-9 (PHQ-9, range 0–27, higher scores indicate greater severity). Stigma was measured with the Explanatory Model Interview Catalogue (EMIC, range 0–30, higher scores indicate greater stigma). Quality of life was evaluated using the WHO Quality of Life-BREF (WHOQOL-BREF, range 0–100, higher scores indicate better quality of life). Mean differences, 95% confidence intervals (CI), and p-values from paired t-tests are reported.

Psychosocial Measure	Baseline Mean ± SD	Week 6 Mean ± SD	Mean Difference (95% CI)	p-Value (paired t-test)
Depression (PHQ-9)	9.2 ± 3.1	7.8 ± 3.4	-1.4 (-2.0 to -0.8)	0.003
Stigma (EMIC)	17.5 ± 5.4	14.8 ± 5.9	-2.7 (-3.6 to -1.8)	0.005
Quality of Life (WHOQOL-BREF)	58.4 ± 11.2	64.7 ± 13.0	6.3 (4.2 to 8.4)	0.004

Note:

All data are in mean ± SD.

The p-value indicates the significance of differences between baseline and Week 6.

Quality of life was assessed using the WHO Quality of Life-BREF (WHOQOL-BREF), transformed to a 0–100 scale, where 100 represents the best possible quality of life.

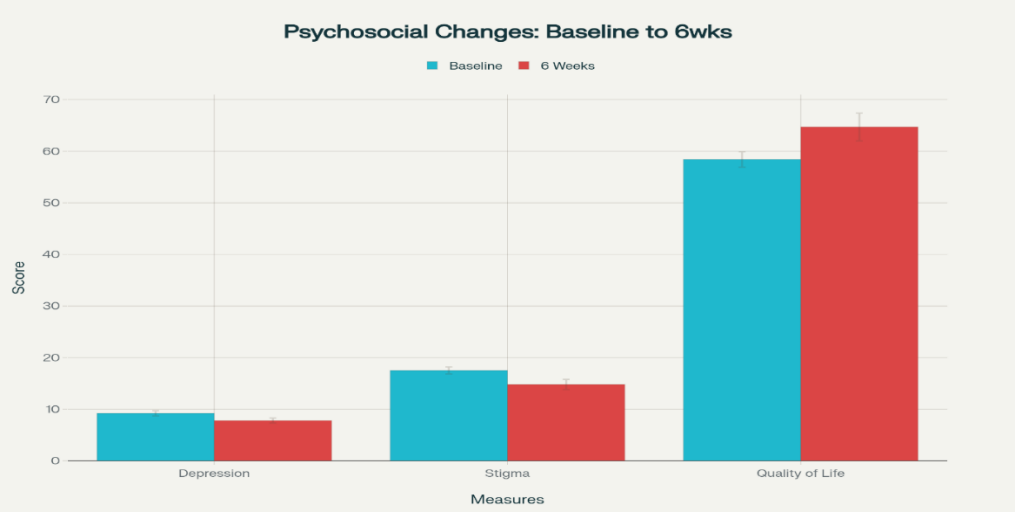

Figure 3: Changes in Psychosocial Outcomes from Baseline to 6 Weeks Post-MDT

This set of bar charts depicts pre-post changes in psychosocial measures for 112 leprosy patients from baseline (MDT completion) to 6 weeks post-treatment. The measures include depression (Patient Health Questionnaire-9 [PHQ-9], 0–27 scale, higher scores indicate greater severity), stigma (Explanatory Model Interview Catalogue [EMIC], 0–30 scale, higher scores indicate greater stigma), and quality of life (WHO Quality of Life-BREF [WHOQOL-BREF], 0–100 scale, higher scores indicate better quality of life). Each measure is represented by paired bars showing baseline and 6-week mean scores, with error bars denoting 95% confidence intervals to indicate the precision of the estimates. The charts visually confirm modest reductions in depression and stigma scores and an increase in quality of life scores, with variability noted across patients.

Adherence to Self-Care and Rehabilitation

Seventy-one percent of patients achieved ≥80% adherence to self-care and rehabilitation practices, as documented in diaries. Higher adherence showed weak correlations with enhanced nerve function scores ($r = -0.18$, $p = 0.09$) and lower stigma ($r = -0.22$, $p = 0.06$), though these did not reach statistical significance, potentially due to sample size limitations and self-reporting biases. Adherence was lower in MB (65%) compared to PB patients (75%; $\chi^2(1) = 2.71$, $p = 0.10$).

Preliminary Oncological Screening

During the brief follow-up, no confirmed cancer cases were diagnosed. As an exploratory measure, screening via symptoms and biomarkers flagged 4 patients (3.6%, all MB) with potential risk indicators, such as persistent non-healing ulcers (n = 2), unexplained anemia on CBC (n = 1), and chronic lymphadenopathy (n = 1), prompting specialist referrals. This low detection rate is consistent with risks manifesting over extended periods rather than acutely.

4. DISCUSSION

This 6-week prospective cohort study demonstrates modest yet variable improvements in clinical and psychosocial domains among leprosy patients following MDT completion, highlighting the heterogeneous nature of post-treatment trajectories in real-world settings. Nerve function and disability scores exhibited overall gains, but these were predominantly confined to PB patients, consistent with prior observations that MB cases, often characterized by higher bacterial loads and baseline impairments, experience persistent or progressive damage despite therapy [2, 3, 6]. For instance, our findings align with Bandeira et al.'s cohort of pediatric patients in Brazil, where reaction progression correlated with neural worsening, though our adult South Indian cohort showed lower overall severity [3]. The observed 18% incidence of reactions, primarily in the early weeks, aligns with reported short-term rates of 10-25% in cohorts from Brazil and India, emphasizing the critical role of early monitoring to avert escalation into new disabilities [3, 11]. Such reactions, managed effectively with corticosteroids in this study, underscore the value of optimized steroid regimens, as evidenced by trials showing comparable efficacy between shorter and longer durations in preserving nerve function while reducing adverse effects [11].

Psychosocial improvements, including reductions in depression and stigma alongside enhanced quality of life, reflect patterns seen in broader reviews where baseline mental health burdens of 20-50% ameliorate with time and support, though societal stigma often perpetuates variability [4, 5]. Our results extend Lusli et al.'s evaluation of psychological support interventions, which demonstrated stigma reductions similar to our EMIC score changes, suggesting that even brief post-MDT follow-up can yield benefits when integrated with community engagement [4]. The modest correlations between adherence and outcomes, while non-significant, echo findings that self-care practices can prevent 20-30% of long-term disabilities, albeit with weaker short-term links potentially masked by self-report biases and limited follow-up [8, 12]. MB patients' lower adherence rates further suggest targeted interventions for this subgroup, addressing barriers like access and education to bolster compliance, as highlighted in qualitative studies from Indonesia [12].

Preliminary oncological screening revealed minimal acute findings, congruent with epidemiological data indicating elevated long-term risks for skin and lymphatic malignancies in lepromatous leprosy, rather than immediate post-treatment manifestations [9, 10]. Our low detection rate mirrors Tokudome et al.'s historical cohort, where cancer mortality was higher in lepromatous cases but emerged over decades, supporting our exploratory approach and the need for extended surveillance [10]. Limitations of this study include the abbreviated timeframe, which captures acute changes but overlooks chronic evolution, potential attrition bias despite non-significant dropout differences, reliance on self-reported adherence, and unmeasured confounders such as comorbidities or socioeconomic factors. Future research should extend follow-up durations, incorporate larger samples for subgroup analyses, integrate objective biomarkers to validate trends, and explore multi-center designs for broader generalizability. These results advocate for multidisciplinary post-MDT programs emphasizing early reaction detection, psychosocial support, and adherence promotion to minimize outcome variability and enhance long-term prognosis, with implications for WHO guidelines in endemic regions.

5. CONCLUSION

This 6-week prospective cohort study demonstrates modest improvements in clinical and psychosocial outcomes post-MDT in leprosy patients, with greater gains in paucibacillary than multibacillary cases, highlighting the need for targeted interventions for the latter. The 18% reaction incidence underscores the importance of early monitoring, while psychosocial

gains and adherence patterns suggest integrated support systems are crucial for sustained recovery. Preliminary oncological screening aligns with long-term risk profiles. These findings advocate for multidisciplinary post-MDT programs focusing on reaction management, psychosocial support, and adherence promotion to optimize outcomes. Future research should extend follow-up and sample size to further elucidate long-term trends and subgroup differences.

6. ACKNOWLEDGMENTS

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