Molecular detection of *Mycobacterium leprae* from skin biopsies of clinically suspected leprosy patients - A prospective cohort study

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ABSTRACT

Introduction: Leprosy is considered as a rare and exotic diagnosis, something the clinician will see only once or twice in a career. Recently, leprosy patients suspected of acquiring the disease autochthonously have been seen throughout India. The study aims to use Real Time Polymerase Reaction (qPCR) to molecularly diagnose *Mycobacterium Leprae* (M. Leprae) from skin biopsies of probable leprosy patients who attend a tertiary care hospital in the Salem district. **Materials and Method:** The present study is a prospective cohort study conducted over the period of 6 months (Jan – June 2024). Forty OPD cases showing cardinal signs of leprosy are included for detecting *M. leprae* specific repetitive regions (RLEP). Patients with other dermatological lesions were excluded from the study. Ethical clearance was obtained from institutional ethical committee (GMKMC&H/114/EC/2023-86). Under local anaesthesia, 3.5mm of tissue from marked area is collected from the patient using punch biopsy & placed in tube containing 70% ethanol. All selected patients also underwent Slit skin smear. From the collected sample, DNA extraction was done and qPCR was performed. Data was analyzed using SPSS software 22.0. **Result:** Among 40 cases, 16 (40%) were confirmed positive for M. leprae DNA & 24 (60%) were identified negative. Of these 16 (40%) positive cases, 9 (22.5%) were male and 6 (15%) were female. It is substantially higher in >40 years of age group with variation in the bacterial load. The positivity rate was higher in multibacillary compared to paucibacillary type. The present study reports 40% of punch biopsy & 10% slit skin smear yielded detectable results using PCR amplification. The clinical and epidemiological features of leprosy patients are analyzed using the Chi square test, which showed statistical significance (p<0.04). **Conclusion:** Our study concludes that qPCR will be helpful for detecting leprosy cases with clinical findings in the field. The study confirms a 40% positivity with 100% specificity.