INFECTIOUS DISEASES (BACTERIAL, FUNGAL, VIRAL, PARASITIC, INFESTATIONS)

DEVELOPMENT AND EVALUATION OF A DROPLET DIGITAL PCR ASSAY FOR THE DIAGNOSIS OF PAUCIBACILLARY LEPROSY IN SKIN BIOPSY SPECIMENS

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Background: The reduced amounts of M. leprae among pacibacillary (PB) patients reflect the need to further optimize methods for leprosy diagnosis. An increasing number of reports have shown that droplet digital PCR (ddPCR) is a promising tool for diagnosis of infectious disease among samples with low copy number. To date, no publications have investigated the specificity and sensitivity of ddPCR detection of M. leprae in clinical samples. The aim of this study was to develop and evaluate a ddPCR assay for the diagnosis of PB leprosy in skin biopsy specimens.

Methods: The two most sensitive DNA targets for detection of M. leprae were selected from electronic databases for assessment of sensitivity and specificity by quantitative PCR (qPCR) and ddPCR. Control patients (n=59) suffering from other dermatological diseases were used to define the threshold of the duplex ddPCR assay. For comparative evaluation, qPCR and ddPCR assays were performed in 33 samples confirmed as PB leprosy.

Results: RLEP and groEL were used to develop the ddPCR assay by systematically analyzing specificity and sensitivity. Based on the defined threshold, the ddPCR assay showed greater sensitivity in detecting M. leprae DNA in PB patients compared with qPCR (85% vs 45%).

Conclusions: We developed and evaluated a duplex ddPCR assay for leprosy diagnosis in skin biopsy samples from PB patients. While still costly, ddPCR may be a more sensitive diagnostic tool for detection of PB leprosy.