

PP-05: Serodiagnosis of *Leishmania donovani* induced cutaneous leishmaniasis: a method comparison study

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Introduction: Sri Lanka reports a large focus of cutaneous leishmaniasis (CL). CL is not known to exert a high humoral response. However, we detected a high seroprevalence for CL in Sri Lanka and developed a cost-effective in-house ELISA assay that has been described previously. This assay is important to detect microscopy negative patients prior to conducting second line investigations and to detect pre-clinical infections in the field. The aim of the current study was to compare the local assay with other known assays.

Methods: Study samples (n=100) were collected randomly from patients with laboratory confirmed CL. Control samples (n=25) were collected through field visits to disease endemic and non-endemic areas. In-house ELISA, DAT, Indian dipstick test and rK39 strip test were carried out on all study samples. The specificity and sensitivity were analysed. The cost analysis was also done per patient.

Results: In house ELISA showed a high seropositivity of 81.0% (n=81/100) while DAT (57.5%; n=23/40), Indian dipstick test (22.0%; n=22/100) and rK39 test (15.0%; n=15/100) showed a comparatively less seropositivity. According to Kappa index values, there was no perfect agreement between tests. Among ELISA positive patients (n=81), DAT, Indian dipstick test and rK39 demonstrated seropositivity rates of 61.3% (n=19/31), 25.9% (n=21/81) and 16.0% (n=13/81), respectively. Among ELISA negative patients (n=19), the three assays demonstrated seropositivity rates of 44.4% (n=4/9), 5.3% (n=1/9) and 10.5% (n=2/19), respectively. The clinico-epidemiological profiles of seropositive patients in each assay were also different. Cost per patient was approximately 5.5 USD for DAT and 3.0 USD for each of the other tests.

Conclusions: In-house ELISA performs better than standard assays in the local setting. DAT can be used as an alternative test when ELISA is not available or negative. This establishes a suitable method for clinical and preclinical screening of CL in Sri Lanka.

Keywords: *Leishmania donovani*, cutaneous leishmaniasis, seroprevalence, serodiagnosis