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Diagnosis of suspected cutaneous leishmaniasis lesions with rapid diagnostic test and slit skin smear: a comparative study

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Cutaneous leishmaniasis (CL), a neglected vector borne tropical infection which causes non-healing skin lesions, is a newly emerged and established disease in Sri Lanka. The main diagnostic technique available for leishmaniasis is skin slit smears (SSS) which is less costly and most commonly used method in laboratories to identify *Leishmania amastigotes* (LD bodies), which has the reported sensitivity between 35-60%. Since this does not warrant adequate accuracy for the detection of the disease, the aim of this study was to compare the sensitivity and the specificity of a newly introduced commercially available Rapid Diagnosis Test (RDT) to detect *Leishmania* antigen in CL lesions with SSS.

Following written informed consent, eighty seven patients with clinically suggestive CL lesions were subjected to parasitological investigations. Slit skin smear was performed in duplicate for all the 87 suspected cases. Parasite count of SSS was obtained in different clinical manifestations in accordance with the WHO grading by double blind method.

In SSS, 49 (56.32%) were positive for LD bodies in suspected CL lesions. RDT were positive only on 24 lesions (27.58%). Most of the samples that were positive by RDT had a parasite count of $\geq 2+$, which may suggest that patients with less than $\leq 2+$ parasitemia may not be detectable by the RDT. These results indicate that the sensitivity of RDT was only 48.9%. This study implies that RDT is positive only with a high parasite count and therefore cannot be recommended to be used to diagnose leishmaniasis in Sri Lanka in patients with a low parasitaemia.

Keywords: Cutaneous leishmaniasis, skin slit smears, Rapid Diagnostic Test (RDT)

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