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A Novel non-invasive method for diagnosis of Post kala-azar dermal leishmaniasis (PKDL) from urine samples by using rK39 strip test

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Post kala-azar dermal leishmaniasis (PKDL), skin dermatitis in treated VL (Visceral Leishmaniasis) patients, is caused by the *Leishmania donovani* protozoan parasite. It is mainly found in East Africa (>50% Sudan & >30%Kenya) and 5–10% Indian subcontinent (India, Bangladesh and Nepal) after successful or irregular treatment of kala-azar (VL). The disease develops in a variety of clinical forms from hypo pigmented macules to infiltrated papules and nodules on the skin of the face, limbs, or trunk. In Indian subcontinent, it manifests after months or several years of remission from infection, while in East Africa it develops within weeks to a few months. Sincekala-azar is anthroponotic in Indian subcontinent, as till date no other reservoir (Animal) has been reported. PKDL Patients are considered as the major reservoir of parasites, which probably has plays an important role in interepidemic periods of VL. So to stop transmission of disease, a reliable non-invasive diagnostic test with proper treat is urgently required to detect cases early. Accurate diagnosis of PKDL still remains a problem for clinicians and coordinators of kala-azar control programs due to similar presentation by other dermatological conditions such as leprosy, vitiligo and fungal infection. Demonstration of parasites in skin biopsy/slit smear or by culture remains the gold standard; however, the methods involved are invasive, painful, require skilled personnel, poorly sensitive, and difficult to perform in field conditions. Blood samples required for confirmation needs its collection in already pre-existing anaemic patients. Moreover it is quite difficult to collect blood in the rural field conditions as most of the patients are illiterate and are afraid of giving blood even for diagnostic purposes. It is another tough proposition to collect blood from very small children and infants in the endemic field setting. There is also great difficulty in collecting blood from healthy contacts and controls, as they are of the opinion that they do not suffer from any disease. In 2 to 5% of PKDL patients, the absence of a history of VL suggests subclinical infection and poses further difficulty for diagnosis. Purely non-invasive method for diagnosis of VL has been reported from sputum and urine samples by using rK39 strip test1-2. To the best of our knowledge, this is perhaps the first study on rK39 strips (InBios, Seattle, WA) test to detect active PKDL cases using urine samples. The sensitivity of dipstick (rK39) test in urine was 95%, 98%, & 100% in macular, maculo-papular and nodular or papulo-nodular type of PKDL cases respectively. The specificity of the test was about 100%.Finally need to early diagnosis and proper management for active PKDL cases are two important strategies of the control and eradication program which is scheduled to end by 2015 and 2018 in the Indian subcontinent. So this diagnostic test will be highly beneficial in difficult field conditions as the test is purely non invasive, uses easily collectable samples, highly sensitive, specific and needs no special equipment or sophisticated technology, and the results can be read visually within 10-15 minutes.