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Evaluations of specificity & sensitivity of rK39 test in Visceral Leishmaniasis and HIV Co-infection

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Abstract

The rK39 strip test is a simple, non-invasive, sensitive and specific test for screening of Visceral Leishmaniasis (VL). Clinically VL-HIV and co-infected 50 parasitological confirm patients enrolled forms RMRIMS, Patna Bihar. The objective behind highlighting this co-infection is for awareness of treating physician to take care of the patients suffering with fever and hepato spleenomegaly might be co-infected with HIV. Other control arm HIV positive patients taken from ART centre RMRIMS Patna and relative of Visceral Leishmaniasis patients who are living with VL-HIV co-infected blood sample has been taken. The sensitivity & specificity of rK39 test in parasitological confirmed VL-HIV co-infected patients was 100% positive and other group in control arm rK39 showed negative result. These results suggest that rK39 strip test shows highly sensitivity & specificity in case of VL-HIV co infection.

Keywords: Visceral Leishmaniasis (VL), HIV, Co-infection, rK39 test.

INTRODUCTION

350 million people are at risk of infection with leishmaniasis in endemic area and approximately 12 million are currently infected. 400,000 new cases are reported each year (WHO). VL is an important protozoan disease in Latin America, Africa, Mediterranean Countries, China, Bangladesh and India. In India, it is common in Eastern sector like- Bihar, West Bengal, Uttar Pradesh, Assam, Sikkim and some part of Jharkhand. Visceral leishmaniasis has occurred primarily in the State of Bihar and approximately 1, 00,000 – 3, 00,000 cases are estimated annually in which 90% Visceral leishmaniasis cases occur in low Socio-Economic group [1-4]. One third of all HIV patients worldwide live in regions where leishmaniasis is endemic [5]. Visceral leishmaniasis caused by the parasite *L. donovani* is endemic in Bihar, a populous state of 110 million people in East India, which carries an estimated 40% of the world's VL burden [6]. Although Bihar has a relatively low prevalence of HIV (between 0.22–0.33%), its high population density means that in absolute numbers an estimated 300,000 people in the state live with HIV/AIDS [7]. Moreover, Bihar is one of the few states in India where the rate of new HIV infections is increasing [8]. This has major implications for VL co-infection: like other opportunistic infections in HIV patients, *Leishmania* amastigotes have evolved strategies to survive and multiply within macrophages [9], which are enhanced by HIV co-infection [10] and accelerate progression of disease [11]. This may help explain why the risk of developing VL is estimated to be between 100 and 2300 times higher in HIV-infected individuals than in those who are HIV-negative [12]. Data on the prevalence of HIV-VL co-infection in India is scarce, although estimates range from 2–5.6% [13-18]. HIV-VL co-infection therefore appears to be a growing public health issue in India. Yet the evidence base regarding best treatment practices for co-infected patients is limited, due to a lack of randomized controlled trials and to the fact that most available data comes from observational studies with relatively short follow-up periods and often with high rates of loss to follow-up [19]. Nevertheless, worse outcomes in almost every respect have consistently been reported in this patient group when compared to patients not known to be HIV-positive—for example, in terms of higher relapse rates, mortality, and VL drug toxicity and resistance [20]. Currently the Indian treatment guidelines for VL do not differentiate treatment of HIV-VL co-infected patients from that of other patients presenting with VL. First-line treatment for all VL patients in India is 28 days of oral miltefosine (where not contra-indicated), although the government is currently assessing the use of single-dose AmBisome and lower-dose combinations therapies [21] as recommended by the World Health Organization (WHO). However, India

has not developed a contingency plan for HIV-VL patients. Thus, in current study focused on specificity & sensitivity of rK39 test in VL-HIV Co-infection to take better remedies to overcome such type of infection.

METHODOLOGY

We were conducted a hospital based cross sectional study at the RMRIMS (Rajendra Memorial Research Institute of Medical Sciences, Patna, Bihar India) from January 2011 to Dec. 2014 to evaluate the sensitivity & specificity of rK39 in HIV-VL Co-infected patients. Detail history of these VL-HIV co-infected patient has been also taken in structured questionnaire patients had complaints with history of prolonged fever (≥ 15 days), loss of appetite, hepatomegaly, spleenomegaly, malnutrition, anemia etc. Also taken migration history, past history of kala-azar, family history of kala-azar, treatment history of kala-azar has been taken. We did serological test that is rK39 rapid diagnostic test (InBios Kala-azar detect in Rapid test, manufactured in the USA by inBios international) VL-HIV co-infected as well control arm group. After screening VL-HIV co-infected cases by using rK39 test, if this test comes positive then we had admitted the patient for confirming the Kala-azar by parasitological either do splenic aspiration / Bone marrow aspiration. Before doing parasitological examination of L.D bodies, we have routinely done the hematological examination like HB gm%, TLC, DLC, Platelet count. Biochemical test like total protien, Liver function test (Serum Bilirubin, SGOT, SGPT), Kidney function Test (Blood Urea, Serum creatinine) Prothrombin time, serum electrolyte Na+, K+, Blood sugar (Fasting and Post Parandial). Testing of HIV I & II also performed simultaneously either of three tests like i.e COMAIDS-RS Advantage ST HIV 1/2 immuno dot test kit manufactured by span Diagnostic Ltd, India. If this test comes positive then 2 another test e.g. PAREEKSHAK HIV1/2 Triline card test manufactured by Bhat Bio Tech India (P) ltd and AIDSLAN. HIV1/2 Trispot Test Kit, Bhat. Bio. Tech, India (P) Ltd did for Confirmation of the HIV I & II.

RESULT

There was no case found positive in case HIV- / VL – in different test conducted in HIV infected VL (Table -1). There was also no case found positive in case HIV+ / VL – in different test conducted in HIV infected VL, in case HIV+ / VL + and HIV- /VL + found positive in different test conducted in HIV infected VL cases (table-1). Sensitivity & specificity of rK39 test in parasitogical confirm patients of after confirming the L.D Bodies either by splenic aspiration /Bone marrow aspiration result, we were started the anti-Leishmaniasis treatment that was Amphotericin-B in the dose of 1 mg/kg body wt. diluted in 5% Dextrose solution alternate day total 15 injection to be transfused, during the time of antileishmanial treatment vital parameters were monitored. Biochemistry & hematological investigation were done at mid of the treatment and end of the treatment. After completing the treatment Bone marrow aspiration has been conducted and results showed LD Bodies negative.

Table1: Serological remarks for controls and HIV infected Patients at VL daiagnosis

Sl. No	Group	No. of Test	Rk39 Test	immuno dot test	Triline card test	Trispot Test Kit	Parasitological Test
1	HIV- /VL -	50	-				-
2	HIV+ /VL -	50	-				-
3	HIV+ /VL +	50	+	+	+	+	+
4	HIV- /VL +	1113	+				+

CONCLUSION

This test used as such can only give an estimated idea about the proportion of people that have had exposure to leishmania parasite infection with HIV, which eventually may suggest the transmission dynamics of the disease that can be used for working out the disease control strategies. Semi quantitative rK39 strip test or quantitative ELISA with rK39 antigen is best method in sero-epidemiological surveys. Results suggested that rK39 strip test shows highly sensitivity & specificity in case of VL-HIV co infection in initial stage of human immune deficiency.

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