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Validity of Katex Test for Diagnosis of Visceral Leishmaniasis

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Abstract

Background: Newly developed KAtex test can be used as a non invasive tool for diagnosis of Kala-azar. **Objectives:** The aim of the present study was to validate the KAtex method to diagnose VL. **Methodology:** This was a cross-sectional study carried out in the Department of Microbiology at Dhaka Medical College, Dhaka, Bangladesh in collaboration with the department of Parasitology at Institute of Epidemiology, Disease control and Research (IEDCR), Dhaka, Bangladesh for a period of one year. Clinically suspected Kala- azar (VL) cases of different age and sex attending IEDCR from different Kala-azar endemic areas of Bangladesh were selected for this study. Microscopy and culture was performed with Bone marrow (BM). KAtex was performed with urine sample. Urine samples taken from cases were pretreated to inactivate heat labile materials which might cause a false positive reaction. Antigen which is detected by KAtex is heat stable carbohydrate antigen. Latex sensitized with antibodies raised against Leishmania donovani antigen was mixed with the urine sample on a glass slide. No agglutination indicates absence of antigen in urine. **Result:** Cases were 130. Among 130 clinically suspected VL cases, 70 (53.85%) cases were BM positive and 60 (46.15%) cases were BM negative. All the 70 BM positive cases were positive by KAtex. Among 60 BM negative cases, 15 were positive by KAtex. The sensitivity of KAtex is 100% and specificity is 75%. Highest percentage (52.86%) of bone marrow positive cases were below 10 years of age group. **Conclusion:** In conclusion, KAtex test is a good diagnostic tool for the detection of VL. [*Bangladesh Journal of Infectious Diseases, December 2017;4(2):45-47*]

Keywords: VL; KAtex; Bone marrow (BM); Kala-azar; *Leishmania donovani*

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Introduction

Visceral leishmanasis (VL), commonly Known as Kala-azar, is a chronic febrile disease caused by Leishmania donovani[1]. The demonstration of the parasite (LD bodies) in the aspirates of the spleen, liver, bone marrow, lymph nodes is the only way to confirm VL conclusively[2]. Sensitivity of bone marrow aspirate smear is estimated to be 70% or lower[3]. Sensitivity of lymph node aspirate is estimated to be 50.0% in Sudan. Sensitivity of splenic aspirate exceeds 90%[4]. But these invasive procedures are time consuming, carries risk of hemorrhage, requires expert persons, and may be false negative if the parasite density is low[5].

Antigen detection is more specific than antbody based immunodiagnostic tests. This method is also helpful in the diagnosis of disease in cases where there is deficient antibody production[6]. Currently a latex agglutination test named as KAtex has been described for the detection of urinary antigens in VL[7]. This test is positive in active cases and it is positive within one week of infection[8]. KAtex becomes negative one month after completion of treatment. KAtex is simply to use, results are available within 2 minutes, and it does not require any electric appliances and is thus feasible in the rural health centres. Collection of urine is acceptable to the patients. Testing of an antigen has moreover a potential for monitoring response to treatment where the antibody based tests are of no help[8]. Therefore, this study was undertaken to evaluate the validity of KAtex in the diagnosis of VL patients.

Methodology

This was a cross-sectional study carried out in the Department of Microbiology, Dhaka Medical College, Dhaka, Bangladesh in collaboration with the Department of Parasitology in IEDCR from July 2006 to June 2007 for one year. Clinically suspected kala-azar (VL) cases of different age and sex attending IEDCR from different kala-azar endemic areas of Bangladesh were selected for this study. Patients having fever for more than 2 weeks, with or without splenomegaly, having history of loss of body weight following onset of fever were clinically suspected as kala- azar cases. Urine and bone marrow aspirations were taken with full aseptic precaution. Urine was collected in a sterile dry test tube for Katex test. Bone marrow (BM) aspiration was done for microscopy and culture was done in N.N.N medium at 24^0c for 1-3 week. Data was collected in a pre designed data sheet. Then data were entered in computer and analyzed by using SPSS program.

Result

Table 1 Shows Bone marrow samples and urine samples were collected from 130 clinically suspected kala–azar cases, 70 (53.85%) cases were bone marrow positive and 60 (46.75%) cases were bone marrow negative. Among 130 cases, 85(65.38%) were KAtex positive and 45(34.62%) cases were KAtex negative.

Table 1: Comparison of KAtex Test with Bone Marrow Culture

KA tex	Bone Marrow Culture		Total
	Positive	Negative	
Positive	TP 70	FP 15	85
Negative	FN 0	TN 45	45
Total	**70**	**60**	**130**

Table 2 shows sensitivity and specificity of KAtex. Sensitivity of KAtex is 100% and specificity of KAtex is 75%.

Table 2: Sensitivity and Specificity of KA tex for diagnosis of VL

Variables	Values	95% CI
Sensitivity	100.0%	94.87% to 100.00%
Specificity	75.0%	62.14% to 85.28%
PPV	82.35%	72.90% to 89.00%
NPV	100.0%	92.13% to 100.0%
Accuracy	88.46%	81.68% to 93.40%

PPV=Positive predictive value; NPV= Negative predictive value; CI=Confidence Interval

Table 3 shows that among 130 clinically suspected VL Cases, highest percentage (52.86%) of bone marrow positive cases were below 10 years of age group.

Discussion

The study was carried out to evaluate the performance of KAtex in the diagnosis of Kala-azar cases and to compare these results with those obtained by BM microcopy and culture. In this study, among 130 clinically suspected Kala-azar cases, 70(53.85%) were BM positive and 60 (46.15) were BM negative. Sensitivity of BM aspirate smear is estimated to be 70% or lower[3]. This coincides with the result in this present study.

Table 3: Age distribution of positive cases among the clinically suspected VL cases

Age Group	Clinically Suspected VL cases	Bone marrow positive cases
<10 Years	47	37(52.86)
11 to 20 Years	12	8(11.43)
21 to 30 Years	30	15(21.42)
31 to 40 Years	21	4(5.71)
41 to 50 Years	10	3(4.2)
>50 Years	10	3(4.24)
Total	**130**	**70**

In the present study, among 130 cases, KAtex was positive in 85(65.38%) cases .All the 70 BM positive cases were KA tex positive. Among 60 BM positive negative cases 15(25%) were KAtex positive. In a study done by Nahar[9] results of BM aspirates and KAtex were compared. In that study all the 68(100%) BM positive cases were KAtex positive. Among 82 BM negative cases 12(14.63%) were KAtex positive in that study. The result of KAtex positivity in BM negative cases in present study is higher than that of Nahar[9]. This is might be due to the fact that in this study, tests were done on freshly collected urine samples. In the study done by Nahar[9], Katex was done on urine samples collected from Mymensingh which were brought to Dhaka.

In another study done in Sudan, all the 15(100%) smear positive cases were KAtex positive. Among 47 smear negative cases 6(12.76%) were KAtex positive and 41 (87.23%) were KA tex negative[10]. The results of KAtex positivity among smear negative cases in Sudan is lower than the present study which may be for the reason that they used both fresh and frozen urine samples. The sensitivity of KAtex is 100.0% and specificity of KAtex is 75.0% in this present study. Vilaplana et al[11] showed 100% sensitivity and 96.0% specificity for KAtex. In a study in Sudan showed 100.0% sensitivity and 87% specificity for KA tex. In separate study on 52 samples from Yemen[10], sensitivity of 86.0% and specificity of 100% for KAtex were reported. In another study conducted by EL-safi et al[7] from Sudan showed 95.2% sensitivity and 100% specificity for KAtex. In the present study, results of KAtex is compatible to other studies.

In this study, among 130 study cases, the highest percentage (52.86%) of bone marrow positive cases were below 10 years of age group. A study was conducted by central disease control (CDC), USA and Institute of Centre for Diarrhoeal disease Research, Bangladesh (ICDDRB) to determine risk feature for Kala-azar. Risk was highest for persons 3-45 year of age[12].

Conclusion

It may be concluded that KAtex test for the detection of leishmania antigen in urine can be used as a non invasive tool for diagnosis of Kala-azar which has a high sensitivity.

References

1. WHO Expert Committee on the Control of the Leishmaniases, WHO Expert Committee on the Control of the Leishmaniases. Meeting, World Health Organization. Control of the Leishmaniases: Report of a WHO Expert Committee. World Health Organization; 1990
2. Park K. Park's textbook of preventive and social medicine. 19th edn. M/S Banarsidas Bhanot publishers, Jabalpur, India ; 2007: pp 256-258
3. Zijlstra EE, Ali MS, El-Hassan AM, El-Toum IA, Satti M, Ghalib HW, Kager PA. Kala-azar: a comparative study of parasitological methods and the direct agglutination test in diagnosis. Transactions of the Royal Society of Tropical Medicine and Hygiene. 1992;86(5):505-7
4. Kager PA, Rees PH. Splenic aspiration. Review of the literature. Tropical and geographical medicine. 1983;35(2):111-24.
5. Goyal RK, Mohapatra TM. Superiority of DAT over ELISA as a diagnostic and seroepidemiological tool for the diagnosis of Indian kala-azar. Indian journal of medical microbiology. 2004;22(1):57
6. Rijal S, Boelaert M, Regmi S, Karki BM, Jacquet D, Singh R, Chance ML, Chappuis F, Hommel M, Desjeux P, Van Der Stuyft P. Evaluation of a urinary antigen-based latex agglutination test in the diagnosis of kala-azar in eastern Nepal. Tropical Medicine & International Health. 2004;9(6):724-9
7. El Safi SH, Abdel Haleem A, Hammad A, El Basha I, Omer A, Kareem HG, Boelaert M, Chance M, Hommel M. Field evaluation of latex agglutination test for detecting urinary antigens in visceral leishmaniasis in Sudan. Eastern Mediterranean Health Journal 2003;9(4):844-855
8. Sarkari B, Chance M, Hommel M. Antigenuria in visceral leishmaniasis: detection and partial characterisation of a carbohydrate antigen. Acta tropica. 2002;82(3):339-48
9. Kamrun N. Diagnosis of VL by detecting Leishmania antigen from urinary sample. (Thesis), BSMMU, 2005
10. Kalon Biological Ltd., Aldershort,Hants, United Kingdom, 2005
11. Vilaplana C, Blanco S, Domínguez J, Giménez M, Ausina V, Muñoz C. Noninvasive method for diagnosis of visceral leishmaniasis by a latex agglutination test for detection of antigens in urine samples. Journal of clinical microbiology. 2004;42(4):1853-4
12. Bern C, Hightower AW, Chowdhury R, Ali M, Amann J, Wagatsuma Y, Haque R, Kurkjian K, Vaz LE, Begum M, Akter T. Risk factors for kala-azar in Bangladesh. Emerging infectious diseases. 2005;11(5):655