Validity of Katex Test for Diagnosis of Visceral Leishmaniasis

Ishrat Sharmin¹, AKM Quamruzzaman², Rezina Parveen³, Rashida Akter Khanam⁴,  
Md. Abdullah Yusuf⁵

¹Assistant Professor, Department of Pathology & Microbiology, Dhaka Dental College, Dhaka, Bangladesh; ²Associate Professor, Department of Physiology, Monowara Shikder Medical College, Shariatpur, Faridpur, Bangladesh; ³Associate Professor, Department of Pathology & Microbiology, Dhaka Dental College, Dhaka, Bangladesh; ⁴Assistant Professor, Department of Microbiology, Shaheed Suhrawardy Medical College, Dhaka, Bangladesh; ⁵Assistant Professor, Department of Microbiology, National Institute of Neurosciences & Hospital, Dhaka, Bangladesh

[Received: 1 January 2017; Accepted: 15 July 2017; Published: 1 December 2017]

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

Correspondence: Dr. Ishrat Sharmin, Assistant Professor, Department of Pathology & Microbiology, Dhaka Dental College, Mirpur-14, Dhaka, Bangladesh; Email: dr.ishrats@yahoo.com; Cell no.: +8801796248873

Conflict of interest: There is no conflict of interest to any of the authors of this article.

Funding agency: The study was not funded by any authority.

Contribution to authors: Dr. Ishrat Sharmin contributed from protocol writing upto article write up. The rest authors revised and corrected the paper.

How to cite this article: Sharmin I, Quamruzzaman AKM, Parveen R, Khanam RA, Yusuf MA. Validity of Katex Test for Diagnosis of Visceral Leishmaniasis. Bangladesh J Infect Dis 2017;4(2):45-47

Copyright: ©2017 Sharmin et al. Published by Bangladesh Journal of Infectious Diseases. This article is published under the Creative Commons CC BY-NC License (https://creativecommons.org/licenses/by-nc/4.0/). This license permits use, distribution and reproduction in any medium, provided the original work is properly cited, and is not used for commercial purposes.
Introduction

Visceral leishmaniasis (VL), commonly known as kala-azar, is a chronic febrile disease caused by Leishmania donovani. 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. Sensitivity of bone marrow aspirate smear is estimated to be 70% or lower. Sensitivity of lymph node aspirate is estimated to be 50.0% in Sudan. Sensitivity of splenic aspirate exceeds 90%. 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.

Antigen detection is more specific than antibody based immunodiagnostic tests. This method is also helpful in the diagnosis of disease in cases where there is deficient antibody production. Currently a latex agglutination test named as KAtex has been described for the detection of urinary antigens in VL. This test is positive in active cases and it is positive within one week of infection. 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. 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 Parastology 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°C 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>
<thead>
<tr>
<th>Variables</th>
<th>Values</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>100.0%</td>
<td>94.87% to 100.00%</td>
</tr>
<tr>
<td>Specificity</td>
<td>75.0%</td>
<td>62.14% to 85.28%</td>
</tr>
<tr>
<td>PPV</td>
<td>82.35%</td>
<td>72.90% to 89.00%</td>
</tr>
<tr>
<td>NPV</td>
<td>100.0%</td>
<td>92.13% to 100.00%</td>
</tr>
<tr>
<td>Accuracy</td>
<td>88.46%</td>
<td>81.68% to 93.40%</td>
</tr>
</tbody>
</table>

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

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 microscopy 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. This coincides with the result in this present study.
In the present study, among 130 cases, KAtex was positive in 85 (65.38%) cases. All the 70 BM positive cases were KAtex positive. Among 60 BM positive cases (52.86%) were KAtex positive. In a study done by Nahar et al 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. This is due to the fact that in this study, tests were done on freshly collected urine samples. In the study done by Nahar, 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 KAtex negative. 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 showed 100% sensitivity and 96.0% specificity for KAtex. In a study in Sudan showed 100.0% sensitivity and 87% specificity for KAtex. In separate study on 52 samples from Yemen, sensitivity of 86.0% and specificity of 100% for KAtex were reported. In another study conducted by El-Safi et al 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 (ICDDR,B) to determine risk feature for Kala-azar. Risk was highest for persons 3–45 year of age.

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


10. Kalon Biological Ltd., Aldershort,Hants, United Kingdom, 2005
