Noninvasive Method for Diagnosis of Visceral Leishmaniasis by a Latex Agglutination Test for Detection of Antigens in Urine Samples

Since the appearance of human immunodeficiency virus (HIV), visceral leishmaniasis (VL) has emerged as an opportunistic infection in developed countries (1, 3, 10). It appears in advanced stages of HIV infection and is supposed to accelerate the progression of AIDS (3, 5, 8). Therapeutic failures and relapses are common.

Accurate diagnosis is usually difficult in HIV-coinfected patients because VL has atypical clinical expressions and because serological diagnosis becomes unreliable (1). Demonstration of the parasite in cultured samples or in stained preparations is considered the “gold standard” (GS) for diagnosis but requires invasive techniques. A noninvasive and accurate test is needed in order to improve diagnosis of VL, especially in individuals with an increased risk of suffering complications after invasive methods (2, 6).

We have evaluated the effectiveness of a rapid latex agglutination test (LAT) (KATEX; Kalon Biological Ltd., Aldershot, Hants, United Kingdom) in the detection of a leishmanial antigen (9) in urine from patients with VL and its usefulness in treatment monitoring.

A bone marrow aspirate and a fresh urine specimen were collected from 85 patients with suggestive clinical symptoms and signs of VL. The demonstration of the parasite by culture or Giemsa stain in bone marrow aspirate was considered the GS.

In 16 out of 89 cases the VL clinical diagnosis was confirmed by the GS (group 1), while in 73 it was not (group 2). Urine samples from 73 patients without any suspicion of VL were collected as negative controls (group 3). The percentages of HIV-infected individuals were as follows: 100% in group 1, 91% in group 2, and 21% in group 3.

The LAT was performed in previously boiled urine specimens according to the manufacturer’s instructions. A clear agglutination was recorded as positive.

All specimens from group 1, three from group 2, and none from group 3 were positive by the LAT (Table 1). One of the three patients from group 2 who tested positive had been diagnosed with VL 1 year before. The sensitivity was 100%, and specificity was 96% (Table 1).

We followed up the cases of 13 of the 16 patients from group 1. A urine specimen was collected each time they came to the hospital, and a bone marrow aspirate was also collected if a VL relapse was suspected. The LAT was performed for all urine samples obtained. The leishmanial antigen could be detected in urine up to 1 year after VL diagnosis in HIV-coinfected patients, probably due to their inability to control the parasitosis (4, 7). Therefore, this technique does not seem very helpful in monitoring treatment and predicting relapses.

However, our results show that the test is a sensitive and specific noninvasive tool for diagnosing VL. It is easy to perform and interpret, so it could be used as a screening test in developing areas and among susceptible populations. However, due to the low number of patients with VL included in our evaluation, further studies are needed to confirm these data.

TABLE 1. Leishmanial urinary antigen detection in different patient groups

<table>
<thead>
<tr>
<th>Patient group</th>
<th>No. of LAT results that were:</th>
<th>Total no. of results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
<td>Negative</td>
</tr>
<tr>
<td>Patients with confirmed VL diagnosis</td>
<td>12</td>
<td>0</td>
</tr>
<tr>
<td>(group 1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients with unconfirmed clinical</td>
<td>3</td>
<td>70</td>
</tr>
<tr>
<td>suspicion of VL (group 2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients providing urine samples</td>
<td>0</td>
<td>73</td>
</tr>
<tr>
<td>(group 3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All patients</td>
<td>15</td>
<td>143</td>
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REFERENCES


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