Brief Report

Evaluation of ID-PaGIA syphilis antibody test

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ABSTRACT

Background: Laboratory diagnosis of syphilis is usually accomplished by serology. There are currently a large number of different commercial treponemal tests available that vary in format, sensitivity and specificity. **Aim:** To evaluate the ID–PaGIA Syphilis Antibody Test as an alternative to other specific treponemal tests for primary screening or confirmation of diagnosis. **Methods:** Serum samples from healthy adults (n = 100) were used for detection of specificity of ID–PaGIA. To evaluate sensitivity of ID–PaGIA serum samples (n = 101) from patients with confirmed or suspected syphilis were tested for syphilis antibodies with FTA-Abs IgM, ID-PaGIA, ELISA IgM and TPHA tests. **Results:** No false-positive results were found with ID-PaGIA. Sensitivity of various treponemal tests was the following: FTA-Abs IgM: 95.5%, ID-PaGIA and ELISA IgM: 94%, and TPHA 75%. The positive and negative predictive values of ID-PaGIA were 100 and 89.5%, respectively. **Conclusions:** Compared with other treponemal tests ID–PaGIA has excellent sensitivity and specificity.

Key words: Syphilis, Treponemal test, Rapid diagnostics

INTRODUCTION

Laboratory diagnosis of syphilis is usually accomplished by serology except when treponemes can be directly detected in material from lesions.[1,2] There are currently a large number of different commercial treponemal tests available that vary in format, sensitivity and specificity.[1,3,4] Since occurrence and frequency of false-positive results vary in different types of tests, it is generally recommended that a positive treponemal test be confirmed with another type of treponemal test.[2,5,6] Thus, laboratory-confirmed cases should have at least two different treponemal tests that are positive.

Particle gel immunoassays (PaGIAs) represent established methods in blood group serology and have been introduced for the detection of infectious diseases.[8] The PaGIA for syphilis testing consists of a microtube that contains a gel matrix and red polymer particles sensitized with recombinant antigens TpN15, TpN17 and TpN47 in a ready-to-use suspension. ID–PaGIA Syphilis Antibody Test is a particle gel immunoassay that is rapid, simple, and easy to use.

METHODS

The aim of this study was to evaluate the ID–PaGIA Syphilis Antibody Test as an alternative to other specific treponemal tests for primary screening or confirmation of diagnosis.

The PaGIA (DiaMed AG, Switzerland) was performed as recommended by the manufacturer. Briefly, a plasma sample (10 μl) was pipetted into the funnel of the microtube, vortexed particles were added, and the mixture was incubated for 5 min. After centrifugation for 10 min the results were read. The presence of red line on the top of the gel surface indicated positive result, the presence of color particles at the bottom of the microtube and absence of agglutinated particles within and on top of the gel indicated negative result.

The specificity of this test was determined with fresh serum samples of 100 healthy persons without known history of syphilis. For confirmation of positive or intermediate/equivocal results in this group, additional treponemal tests were performed: ELISA IgM (Euroimmun, Germany), TPHA (Human GmbH,

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Table 1: Results of treponemal tests in a group of patients suspected of having syphilis

Number of tests with positive results	Tests with positive results	Number of cases	False positive cases
0	-	28	
1	ELISA	2	1
	FTA-Abs	8	5
2	ID-PaGIA and ELISA	2	0
	ID-PaGIA and FTA-Abs	1	0
3	ID-PaGIA and ELISA and FTA-Abs	10	0
4	ID-PaGIA and ELISA and FTA-Abs and TPHA	50	0

Germany) and FTA-Abs IgM (BAG, Germany). This study was carried out between November 2003 and March 2005.

To determine the sensitivity of the ID–PaGIA Syphilis Antibody Test, serum samples from the following patient groups were collected in the Dermatology Clinic of Tartu University Hospital – untreated clinically suspected syphilis (n = 30), primary syphilis (n = 12), secondary syphilis (n = 4), early latent syphilis (n = 31), late syphilis (n = 3) and sexual partners of persons with confirmed syphilis (n = 21). All these serum samples were analyzed for *T. pallidum* antibodies by TPHA, FTA-Abs IgM, ELISA IgM, and ID-PaGIA.

RESULTS AND DISCUSSION

In a screening group of serum samples from healthy persons (n = 100), one sample was positive by ID-PaGIA. This sample was confirmed as positive by other tests (ELISA, TPHA, and FTA-Abs) also and was considered as a real positive case. Thus, ID-PaGIA has 100% specificity and was able to detect one real syphilis case in this group.

In the group of patients with suspected or confirmed syphilis, 28 samples were negative for all four treponemal tests and were also considered healthy according to clinical data [Table 1]. Sixty-three samples were positive by at least two different treponemal tests; therefore, the criteria for confirmed laboratory diagnosis of syphilis were fulfilled. A clinical diagnosis of syphilis was also made in all of these patients. ID-PaGIA was positive in all these cases with 100% sensitivity according to the laboratory criteria for syphilis. In 10 cases only one treponemal test was positive. By evaluating the clinical and laboratory data, we found that six cases were considered to be false positives. Four patients were clinically healthy but specific antibodies could be present in their sera as three had been treated for syphilis according to their case history and one was born to a mother who was positive for syphilis by serology (congenital syphilis could not be confirmed). Thus, including the potential serologically positive cases, sensitivity of various treponemal test were the following: FTA-Abs IgM 95.5%, ID-PaGIA 94%, ELISA IgM: 94% and TPHA 75%. The positive and negative predictive values of ID-PaGIA were 100 and 89.5% respectively.

In our study, the ID-PaGIA showed sensitivity similar to that of ELISA and FTA-Abs but higher than that of TPHA. However, this test is advantageous because it is simple to perform, has few equipment requirements (only centrifuge is needed) and short reaction time (only 20 min). Our results are in accordance with a previous study by Schmidt where PaGIA demonstrated high sensitivity and specificity (91.9 and 99.8%, respectively).[9] In another published study, PaGIA was used for screening blood donors and similar high sensitivity and specificity levels were reported.[10]

Although FTA-Abs was more sensitive in detecting antibodies in some previous cases successfully treated for syphilis, it was also associated with more false positive cases and was more difficult to interpret. TPHA was highly specific, but was less sensitive compared with other treponemal tests.

In conclusion, ID-PaGIA Syphilis Antibody Test has excellent sensitivity and specificity and can be used as a test for primary screening as well as for confirmation of diagnosis. Compared to other tests such as ELISA and FTA-Abs, this assay has the advantage of being simple to operate.

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