e-ISSN: 0976-822X, p-ISSN:2961-6042

Available online on http://www.ijcpr.com/

International Journal of Current Pharmaceutical Review and Research 2025; 17(11); 848-851

Original Research Article

Tests for Syphilis and Their Relevance in the Current Scenario

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Received: 18-09-2025 / Revised: 17-10-2025 / Accepted: 18-11-2025
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Conflict of interest: Nil

Abstract:

Background: Syphilis is a systemic infectious disease of variable chronicity. The diagnosis is usually confirmed by serological tests. There is a need for simple and effective rapid point of care tests for screening as well as confirmation. As these tests have not been studied extensively in the Indian scenario, this study was done to evaluate the efficacy of Syphicheck-WB in a tertiary care hospital in Madurai, Tamil Nadu.

Methods: Two hundred consecutive, consenting patients attending STD clinic were selected for the study. These included patients with a clinical suspicion of syphilis, those with other STDs, patients with high-risk behaviour and partners of patients with STDs. TPHA and Syphicheck-WB were done on the blood samples collected from these patients and the sensitivity, specificity, positive predictive value and negative predictive value of Syphicheck-WB were calculated with TPHA as the reference test.

Results: With TPHA as the gold standard, the sensitivity, specificity, positive predictive value and negative predictive value of Syphicheck-WB were 90.4%, 99.3%, 97.9% and 96.7% respectively.

Conclusion: High values of sensitivity and specificity of Syphicheck-WB were recorded in our study. Thus, we conclude that this test can be used as an effective rapid confirmatory test in the Indian scenario which is easier to perform and more cost effective than TPHA.

Keywords: Syphicheck-WB, TPHA, Rapid, Serodiagnosis, Syphilis.

Introduction

Syphilis is a systemic infectious disease of variable chronicity.[1] It is caused by the spirochete Treponemapallidum (T. pallidum). The disease is usually transmitted through the sexual route.[2] There are bouts of active disease with variable periods of latency and the patient can be infectious even in the absence of clinically apparent illness. It is one of the most prevalent Sexually Transmitted Diseases (STD) in large cities in India with clustering of cases in these cities due to increased opportunities for the spread of the disease in such locales.

Serological tests are done to confirm a case of suspected syphilis. [3,4,5] This serodiagnosis begins with simple non-specific non-treponemal tests such as Rapid Plasma Reagin (RPR), which is used extensively for screening. But the specificity of such tests are low and hence they need to be confirmed with specific treponemal tests which detect antibodies against T. pallidum. Treponema Pallidum Haemagglutination Test (TPHA) is one such test used widely in many reference labs. But these tests are technically demanding, time consuming and not widely available in all points of health delivery.

Simple, easy to perform and rapid diagnostic tests are now widely available. These can potentially replace the existing specific treponemal tests and help in the STI control program in India to tackle the spread of sexually transmitted infections. But there are few studies which have evaluated the efficacy of such tests in the Indian population.

This study was undertaken to evaluate the efficacy of Syphicheck-WB in a tertiary care hospital in South India. This is a rapid immuno-chromatographic test which detect both IgM and IgG group of specific antibodies against T. pallidum.

Materials and Methods

This is a prospective study which was conducted in the department of STD in a tertiary care hospital in South India during a period of six months from September 2012 to February 2013.

A total of 200 consecutive, consenting patients were included in the study. The participants were selected according to pre-determined inclusion criteria. Patients who were clinically suspected to have syphilis, those with a history of high-risk behaviour, paediatric patients with signs and symptoms of syphilis, women with bad obstetric histories, HIV positive patients undergoing initial evaluation, patients with other STDs and partners of patients with STDs were included in the study. The patients who were already diagnosed to have syphilis and those who were undergoing treatment or had already undergone treatment were excluded.

A predetermined proforma was filled up for the patients and two blood samples were collected and sent for serological testing. Syphicheck-WB and IMMUTREP-TPHA tests were done by two different lab technicians with previous training in the procedure and interpretation of these tests. Thus, observer bias was avoided. The sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were calculated using TPHA as the reference standard.

Results

In our study, out of the 200 patients 131 (65.5%) were male, 65 (32.5%) were female and four (2%) were transgenders (Table 1).The common age group was between 31-50 years (56.5%) (Table 2).There were 173 married patients in our study which constituted a bulk of 86.5% of the total, with single patients constituting 12% and children constituting 1.5% (Table 3). Upto 68% denied high risk exposures like premarital or extramarital contact, with 15.5% admitting to premarital exposure, 9% to extramarital contact and 7.5% to both. of the patients with history of high-risk sexual exposure, majority gave a history of unprotected contact. Also 6% of the patients admitted to homosexual behaviour. Among the 200 patients, 97 (48.5%) were reactive for HIV. Of the 200 patients, 52 (26%) were positive and 148 (74%) were negative for syphilis serology when tested using IMMUTREP-TPHA. When Syphicheck-WB was conducted, 48 (24%) were positive and 152 (76%) were negative. With IMMUTREP-TPHA as the gold standard, the sensitivity, specificity, PPV and NPV of Syphicheck-WB was 90.4%, 99.3%, 97.9% and 96.7% respectively (Table 4). The kappa coefficient was 0.92.

Table 1: Gender distribution

Sex	No. of patients	Percentage
Male	131	65.5
Female	65	32.5
Transgender	4	2

Table 2: Age distribution and its percentage

Age in years	No. of cases	Percentage
<10	3	1.5
11 - 30	50	25
31-50	113	56.5
51-75	34	17
Total	200	100

Table 3: Marital status

	No. of patients	Percentage
Child	3	1.5
Married	173	86.5
Single	24	12
Total	200	100

Table 4: Sensitivity and specificity of syphicheck

		TPHA		
		Positive	Negative	Total
SYPHI Check	Positive	47	1	48
	Negative	5	147	152
	Total	52	148	200

Discussion

The aim of our study was mainly to assess the feasibility of Syphicheck-WB as an alternative to TPHA which is currently the gold standard diagnostic test to confirm a case of syphilis.

In our study the percentage of males was 65.5% and that of females was 32.5%, which is similar to the studies by Nair et al [6] and Saikia et al [7] showed a prevalence of 33.9% female patients which is in concurrence with the prevalence of our study. The relatively lower number of female cases in our study despite the theoretical high vulnerability of women

to STIs may indicate the hesitancy to seek out STI health services due to social, economic and logistic factors.

The patients in the age group of 31-50 years constituted 56.6% of the total in our study. This age is greater than the 21-30 years and 15-34 years which were reported in other studies. [6,7] This variation may be due to the increased awareness among the younger age group about safe sex practices as they are mainly targeted by mass media campaigns.

More than 80% of our patients were married with many having a history of unprotected sex. Also, there was an erroneous view that unprotected sex with a casual partner was safer than the same with a commercial sex worker. Occupation wise, daily wage labourers formed the bulk of the patients in our study. This is also reflected in the study done by Saikia et al [7]

In our study the sensitivity of Syphicheck-WB was 90.4% which is higher than the 74.48% sensitivity reported in the study by Jafari Yalda et al. [8] The specificity of 99.3% in our study is similar to the study done by Jafari Yalda et al with 99.14%. Our study's results are comparable to these studies in terms of efficacy of the rapid test.

According to the study by BhanuMehra et al [9] the discrepant results between rapid tests and TPHA can be explained by the large number of treponemal antigens which are exposed during the TPHA test. Thus, some cross reaction may occur with other organisms.

Syphicheck-WB is a rapid diagnostic test which is specific, affordable and user friendly. The results can be communicated to the patient within an hour. Thus, it will prevent the loss of follow up and also allow for the same day treatment for both the patient as well as the partner. It does not require specimen dilution and has less variability, whereas TPHA requires diluents and control cells. Syphicheck-WB is more flexible as either whole blood or plasma may be employed while TPHA requires serum for testing. The results of Syphicheck-WB can be interpreted with less observer variation whereas with TPHA there is a higher chance of inter observer variation and bias in the interpretation of results. The reagents in Syphicheck-WB are stable within a wide temperature range of 4-30°C while TPHA reagents must be stored in 2-8°C. The cost of Syphicheck-WB for one patient was Rs. 17.00 in comparison with Rs. 17.50 for TPHA. TPHA in addition requires microtitre pipettes and microtitre plates as initial investment. Hence Syphicheck-WB has a higher cost benefit ratio than TPHA. The kappa coefficient is a measure of agreement between two tests. In our study the value of 0.92 denotes an excellent strength of agreement between Syphicheck-WB and IMMUTREP-TPHA.

Limitations

Syphicheck is positive in both current and old infections. Hence a positive result must be interpreted with the clinical status of the patient.

In early primary syphilis where antibody levels are low, syphicheck can give a false-negative result. One needs to repeat test after 2 weeks if there is strong clinical suspicion of syphilis.

Conclusion

In developing countries like India where trained manpower, resources, access to accredited laboratories are limited and where risk of losing the patient to follow up is more, it can be concluded that these rapid Point of Care tests may be particularly relevant. SYPHICHECK may be used as an alternative to TPHA to confirm a case of syphilis as it has specificity which is on par with that of TPHA. Almost all the specific tests still cannot differentiate between active and treated syphilis, necessitating the need for quantitative treponemal tests to determine recent infection. Stillmulti-centric studies are required before these tests are used as routine confirmatory tests on a large scale as part of countrywide STI control programme. Periodic quality control tests of SYPHICHECK should be put in place before SYPHICHECK is introduced as a diagnostic tool in public health system projects.

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