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Can a Rapid Test Justify as a Screening Test for Syphilis in Hard-To-Reach Population? Its Evaluation

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Abstract:- Introduction: Syphilis has re-emerged as a global public health threat with an estimated 6 million new cases every year. Asymptomatic nature of infection for a considerable time is a major reason for spread and challenge for prevention. Early diagnosis and treatment especially in hard-to-reach populations is essential for its control. Aim of this study was to evaluate the performance of rapid test for syphilis among the attendees in a sexually transmitted infection clinic.
Material & Methods: The study was conducted from September 2022 to August 2023 at Government Medical College and Hospital Nagpur. It was a prospective cross-sectional study wherein 118 patients of clinically suspected syphilis attending the regional center for STI were tested by rapid test for qualitative detection of IgM, IgA, IgG antibodies to Treponema pallidum (Syphicheck: Oscar, Delhi India). Evaluation of the rapid test was done using Treponemal Pallidum Hemagglutination Assay (TPHA) as gold standard. Non treponemal test namely Venereal Disease Research Laboratory (VDRL) was also performed.
Results: Out of 118 serum samples TPHA was positive in 52 samples, negative in 63 samples and indeterminate in 3 samples. The 3 indeterminate samples were excluded from evaluation of the other two tests. Out of 115 serum samples, in 52 samples a positive rapid test was in agreement with TPHA giving a sensitivity of 100%. In 3 samples rapid test was positive but TPHA was negative giving a specificity of 92.64%. The positive and negative predictive value of rapid test were 89.65% and 100% respectively. A reactive VDRL test correlated with TPHA in 46 samples giving a sensitivity of 88.46%. It was reactive in 11 samples which were negative by TPHA giving a specificity of 82.53%. All these 11 samples were positive in a low titre of ≤ 1:4.
Conclusion: Sensitivity and specificity of rapid test was 100% and 92.64% whereas positive and negative predictive values were 89.65% and 100% respectively. The rapid test was easy to perform, required no technical expertise and is suitable for hard-to-reach population.

Keywords:- *Syphilis, Treponema Pallidum, VDRL, TPHA.*

I. INTRODUCTION

Syphilis caused by Treponema pallidum (TP), is a major public health problem which if left untreated can lead to significant complications. Syphilis also facilitates acquisition and transmission of human immunodeficiency virus [1-3]. Globally each year an estimated 6 million new cases of syphilis occur in persons aged 15 to 49 years [4]. Rising incidence of syphilis among women is of great concern due to its impact on pregnant women and their foetuses. Additionally, increase in syphilis has been seen among key populations like men who have sex with men (MSM) [5].

To reduce the burden and impact of this disease routine screening and early treatment is very important. Screening early in pregnancy, treating syphilis infected pregnant women, and avoiding reinfection can help in preventing congenital syphilis [6,7]. However, traditional methods require equipment's and trained staff for conducting and interpretating the tests, and hence have limited use in low-resource settings in developing countries. In addition to this traditional test take time in diagnosis of infection and thus in turn miss opportunity to treat and intervene at earliest [8]. The aim of this study was to evaluate the performance of rapid test for syphilis among the attendees of sexually transmitted infection (STI) clinic

II. MATERIALS AND METHODS

The study was conducted from September 2022 to August 2023 at Government Medical College and Hospital Nagpur**.** It was a prospective cross-sectional study wherein 118 patients of clinically suspected syphilis attending the regional center for STI. Serum samples from each patient were tested by rapid test (Syphicheck: Oscar, Delhi India), a non-treponemal test namely Venereal Disease Research Laboratory test (VDRL antigen procured from The Institute of Serology, Calcutta) and a specific test namely Treponemal Pallidum Hemagglutination Assay (Fortress Diagnostics Ltd, UK). All three tests were performed as per manufacturer's instructions. Treponema pallidum was considered gold standard for evaluation of the other two tests.

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III. RESULTS

Out of 118 serum samples TPHA was positive in 52 samples, negative in 63 samples and indeterminate in 3 samples. The 3 indeterminate samples were excluded from evaluation of the other two tests. Out of 115 serum samples, in 52 samples a positive rapid test was in agreement with TPHA giving a sensitivity of 100%. In 3 samples rapid test was positive but TPHA was negative giving a specificity of 92.64%. The positive and negative predictive value of rapid test were 89.65% and 100% respectively (Table 1). A reactive VDRL test correlated with TPHA in 46 samples giving a sensitivity of 88.46%. It was reactive in 11 samples which were negative by TPHA giving a specificity of 82.53% (Table 2). All these 11 samples were positive in a low titre of ≤ 1:4.

Comparing table 1 and 2 the performance of rapid test was found to be superior to VDRL test.

Table 1: Evaluation of rapid test with respect to TPHA test

	TPHA test +	**TPHA test -**	**Total**
Rapid test +	52	3	55
Rapid test -	0	60	60
Total	52	63	115

Sensitivity-100% **Specificity**- 92.64% **PPV**- 89.65% **NPV**-100%

Table 2: Evaluation of VDRL test with respect to TPHA test

	TPHA test +	**TPHA test -**	**Total**
VDRL test +	46	11	57
VDRL test -	06	52	58
Total	52	63	115

Sensitivity- 88.46% **Specificity**- 82.53% **PPV**- 80.70% **NPV**- 89.65%

IV. DISCUSSION

In recent years, point of care tests for syphilis has gained lot of importance. They are rapid, easy to perform, require no technical expertise in interpretation and no costly infrastructure is required. They can be undertaken in low resource settings and in hard to reach to population. Additionally, it will offer opportunity to administer treatment on the same day of testing. This can interrupt potential transmission to sexual partner or foetus in case of pregnant women. This practice is now accepted as the risk of overtreatment is more acceptable than the risk of non-treatment of syphilis [9].

In the present study sensitivity and specificity of rapid point of care test 'Syphicheck' against a standard reference test TPHA was 100% and 92.64% respectively. The positive and negative predictive value of rapid test were 89.65% and 100% respectively.

A systematic review and meta-analysis conducted by Jafari et al using serum and whole blood showed sensitivity of Syphicheck to be 74.48% and 74.47% while specificity to be 99.14% and 99.58% respectively using TPHA test as gold standard [9]. While the specificity was comparable, a higher sensitivity was observed in the present study.

Schwartz et al showed the sensitivity and specificity of Syphicheck to be 88.2% and 99.6% respectively against a gold standard test fluorescent treponemal antibody absorption test (FTA-Abs) [10]. The positive predictive value and negative predictive value of Syphicheck in this study was 95.7% and 98.8%.

A multicentric study conducted by Mabey et al evaluated four rapid diagnostic tests in four countries. Sensitivity and specificity of Syphicheck in this study ranged from 70.8% to 97.6% and 99.1% to 99.7% respectively using whole blood and for serum it ranged from 67.4% to 97.6% and 98.4% to 98.9% respectively [11].

While Syphicheck was used as a rapid test in the present study and also by many investigators discussed above other rapid tests like Omega VISITECT, Standard BIOLINE, Abbott Determine, Fujirebio Espline and Diesse Syphilis Fast tests have also been evaluated.

The Sexually Transmitted Disease Diagnostics Initiative (SDI) programme evaluated 6 rapid tests Omega VISITECT, Standard BIOLINE, Abbott Determine, Fujirebio Espline, Diesse Syphilis Fast tests and Qualpro Syphicheck which showed sensitivity and specificity as 85.0%, 95.0%, 97.2%, 97.7%, 86.0%, 84.5% and 98.0%, 94.9%, 94.1%, 93.4%, 92.8%, 97.7% respectively [12].

In the present study, performance of rapid test was found to be superior to VDRL test as shown in Table 1 and Table 2.

V. CONCLUSION

The Syphicheck test evaluated in this study shows good sensitivity and specificity to determine treponemal antibodies in serum samples. Therefore, rapid tests being easy to perform and interpret will help in control of syphilis in global settings with limited access to laboratories or screening for syphilis.

LIMITATIONS

A positive test does not necessarily mean a recent or active infection as this test detects both past and present antibodies IgG, IgM and IgA. Thus, these tests cannot be used as tracking tests in areas of high prevalence where already people had syphilis and have been treated and cured of it and will still test positive with rapid tests.

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