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Comparative Evaluation of VDRL Test and Point-of-Care Test (POCT) for the Diagnosis of Syphilis in Pregnant Women

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STRACT

ound: Syphilis is a venereal disease caused by Treponema pallidum affecting 12 million each year, worldwide. Treponema pallidum cannot be cultivated in vitro and is thus diagnosed ly by; direct demonstration of treponemes based on dark field microscopy, Polymerase chain (PCR) and/or serology methods.

s: A total of 100 serum samples from women attending antenatal clinic for syphilis screening ken. VDRL test and syphilis rapid card (POCT) were performed as per the manufacturer's l. TPHA test was performed for the confirmation.

All the 100 antenatal patients were screened for syphilis using VDRL, Syphilis card test , and confirmation was done by TPHA. Three samples were reactive by both VDRL and giving a positivity of 3%. Those three samples positive by the VDRL and POCT were also by TPHA test.

Antenatal syphilis screening with immunochromatographic assays, along side the Conclusion: confirmatory tests such as TPHA, offers a cost-effective solution, and further research is recommended to assess its feasibility and wider application in peripheral health settings.

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Introduction

Syphilis is a curable venereal disease caused by the spirochete *Treponema pallidum*, affecting approximately 12 million people globally each year (1). In India, syphilis and chancroid were predominant causes of genital ulcer disease (GUD) in the 1970s and early 1980s. However, with the identification of human immunodeficiency virus (HIV) in the late 1980s, the pattern of sexually transmitted infections shifted from bacterial to viral. Although there has been a general decline in syphilis prevalence in recent years, it remains a significant public health issue in developing countries like India (2). Additionally, syphilis plays a critical role in the transmission of HIV by increasing viral shedding (3).

Syphilis can be transmitted through direct sexual contact, blood transfusion, or trans-placentally from mother to infant. The disease progresses through primary, secondary, latent, and tertiary stages (4). As *Treponema pallidum* is difficult to cultivate in vitro, diagnosis relies on clinical evaluation, direct demonstration using dark field microscopy, serological tests and molecular biology methods like PCR (5).

Serological tests for syphilis include specific Treponema pallidum tests such as the hemagglutination assay (TPHA), Treponema immobilization pallidum test (TPI), fluorescent treponemal antibody (FTA) test, as well as non-specific tests like the Venereal Disease Reference Laboratory (VDRL) test and Rapid Plasma Reagin (RPR) test. Antibodies to Treponema pallidum typically become detectable 3 to 4 weeks after exposure. Non-treponemal tests, which measure anti-lipoidal antibodies against cardiolipin and lecithin-like antigens released from damaged host cells, are sensitive in early syphilis but have limitations, including biological falsepositive reactions, false-negative results due to the prozone phenomenon, and reduced sensitivity in late stages of infection (6, 7).

Recent interest in point-of-care testing (POCT) for syphilis has emerged, particularly for antenatal screening. One such test is a solid-phase immunochromatographic assay that qualitatively detects all isotypes (IgG, IgM, IgA) against *T. pallidum*. This treponemal POCT can be performed in peripheral settings, offering rapid, cost-effective results and enabling immediate treatment.

This study aims to evaluate the utility of a rapid immunochromatographic assay as a POCT for antenatal screening of syphilis by comparing it with VDRL test and then confirming the results with a more confirmatory test, i.e. TPHA.

Materials and Methods

This descriptive, cross-sectional study was conducted in the Serology Section of the Department of Microbiology at University College of Medical Sciences and associated Guru Teg Bahadur Hospital, Delhi, from April 2024 to July 2024. A total of 100 serum samples from the pregnant women coming for first antenatal visit at Guru Teg Bahadur Hospital were recruited. Participants with a previous history of syphilis or any known contact history were excluded.

Sample collection

Sera separated from the blood samples of all cases were stored at -20 °C until further processing. The performance of the IMMUNOPAK Syphilis card test (RECKON DIAGNOSTICS PVT LTD) was compared with the VDRL test (TREPOLIPIN), and positive results were further confirmed with TPHA (PLASMATEC). All tests were performed according to the manufacturer's instructions.

Sera Preparation

Blood samples were collected in plain vacutainers, allowed to clot for 15 minutes, and

centrifuged for 10 minutes at 2000 g. The VDRL, Immunopak POCT and TPHA were performed according to the manufacturer's recommendations.

Statistical Analysis

Data collected was recorded in Microsoft Excel sheet. The prevalence of syphilis in different antenatal age group was reported as percentage.

Results

Syphilis screening was conducted on 100 antenatal patients using both the Venereal Disease Research Laboratory (VDRL) test and a Point-of-Care Test (POCT). The study population comprised 200 antenatal women, aged 18-44 years, with the largest proportion (36%) falling within the 25-29 age range, followed by 29% in the 20-24 range, and 21% in the 30-34 range. Positive results were confirmed using the *Treponema pallidum* Hemagglutination Assay (TPHA). Of the patients tested, three were positive on both the VDRL and POCT, reflecting a 3% positivity rate. This result was further validated by the TPHA, confirming the same 3% positivity rate (Figure 1).

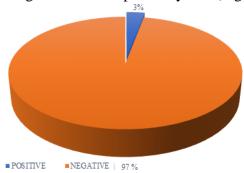


Fig 1. Prevalence of positive syphilis cases in antenatal screening.

Discussion

Syphilis, a curable sexually transmitted infection caused by *Treponema pallidum*, remains a critical

public health concern, particularly in developing countries where its prevalence is higher. The ability to detect and treat syphilis early effectively during pregnancy is vital to preventing adverse outcomes for both the mother and the newborn.

In syphilis infection, IgA antibodies tend to emerge early, but they are not as frequently detected for diagnosis compared to IgM and IgG. IgM antibodies typically become detectable within 1 to 2 weeks after infection, marking the body's initial immune response. IgA antibodies, while also part of the early immune reaction, often appear around the 2nd or 3rd week of infection (8). Despite their presence in the acute phase, IgA is not routinely monitored in diagnostic protocols, as most tests focus on the more clinically significant IgM and IgG antibodies (8, 9).

A notable advantage of point-of-care testing (POCT) over the VDRL test lies in its capacity to detect IgA antibodies, which serve as reliable indicators of active syphilis infections. Incorporating IgA testing into POCT has been shown to significantly enhance diagnostic accuracy (10). Here are a few studies done on the evaluation of Point-of-Care Tests (POCTs) detecting IgG, IgM, and IgA for syphilis diagnosis.

A study done by Zhou et al. (2020) concluded that IgA is a promising biomarker for the rapid diagnosis of syphilis in pregnant women, which facilitates timely treatment and improves maternal health outcomes (11). Collectively, these findings illustrate the value of POCT in offering a more comprehensive evaluation of syphilis infections compared to traditional VDRL testing.

In our study, 100 pregnant women were screened using both the VDRL test and the POCT. Our results showed that three patients tested positive with VDRL and POCT, which represents a 3% positivity rate. These results were subsequently confirmed by TPHA, corroborating the reliability of both the VDRL and POCT tests. These finding align with previous studies that highlights the efficacy of these tests in different settings.

Table 1.	Age distribution	or women	screened for	antenatai sypniiis.

Age Group (Years)	Number of Women Screened	Percentage of Total Screened
15-19	03	3%
20-24	29	29%
25-29	36	36%
30-34	21	21%
35-39	08	8%
40-44	03	3%
Total	100	100%

The findings of our study align with those of Kashyap et al. (2015), who evaluated the effectiveness of immunochromatographic assays as rapid point-of-care tests for antenatal syphilis screening (12).They reported that immunochromatographic assays used in conjunction with a confirmatory test provide a rapid and effective method for detecting syphilis, supporting their use in settings where immediate results are essential like infield settings.

A study by Bristow et al. (2020) reported that rapid diagnostic tests, including immunochromatographic assays, can offer reliable screening for syphilis in low-resource settings, similar to our findings (13). The study found that rapid tests could effectively identify syphilis with performance comparable to traditional methods when used in conjunction with confirmatory tests like TPHA.

Moreover, the study done by Rodolfo et al. (2018) supports our results by emphasizing that while non-treponemal tests like VDRL are widely used for initial screening, they are often complemented by treponemal tests to confirm positive results due to their limitations, such as false-positive and false-negative reactions (14). This study corroborates the need for confirmatory testing and suggests that instead of VDRL, rapid tests such as POCT can serve as a valuable initial screening tool, provided that positive results are validated by more specific assays.

The POCT offers several advantages over traditional methods. It is rapid, easy to use, and

well-suited for peripheral healthcare settings where laboratory infrastructure may be limited besides also detecting IgA antibodies (2-3 weeks). This is consistent with the findings of Dana et al. (2021), which highlighted the practicality and effectiveness of point-of-care tests in antenatal care settings (15). These tests allow for immediate results, facilitating timely treatment and potentially improving outcomes by reducing the delay between screening and treatment initiation.

Despite the promising results, this study has limitations, including the small sample size and the singular focus on a tertiary care setting. Further research involving larger, multi-center trials is essential to fully assess the performance and feasibility of POCT in diverse healthcare environments. Additionally, economic evaluations are needed to determine the cost-effectiveness of implementing rapid tests in routine antenatal care.

Conclusion

The comparative evaluation of the VDRL test and POCT in this study demonstrates that rapid immunochromatographic assays are a promising tool for antenatal syphilis screening. The POCT's rapidity and ease of use make it a good option, particularly when complemented by confirmatory tests like TPHA. Continued research and evaluation will be crucial in establishing best practices for integrating these tests into public health strategies for syphilis control and prevention.

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Ethics approval and consent to participate

Not needed.

Conflict of interest

None declared.

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