On-site screening for maternal syphilis in an antenatal clinic

S. D. DELPORT

Abstract ***Study objective.*** **To determine the sensitivity, specificity, negative predictive value and positive predictive value of the rapid plasma reagin (RPR) test as performed on site in an antenatal clinic to facilitate immediate diagnosis and treatment of maternal syphilis.**

Design. **Open, descriptive study.**

Setting. **Antenatal clinic, Kalafong Hospital, Pretoria.**

Patients. **One thousand two hundred and thirty-seven pregnant patients attending an antenatal clinic for the first time were entered into the study.**

Methods. **An RPR test was performed on site in the antenatal clinic and by the reference laboratory where a *Treponema pallidum* haemagglutination test was also performed.**

Measurements and results. **The results of the RPR test were compared with results reported by the laboratory for sensitivity, specificity, negative and positive predictive values. The RPR test performed on site had a sensitivity of 92,8%, a negative predictive value of 99,5%, a specificity of 96,3%, and a positive predictive value of 64,7%.**

Conclusion. **Maternal syphilis can be diagnosed in the majority of cases during the first visit to an antenatal clinic.**

S Afr Med J 1993; **83:** 723-724.

Pregnant women may seek antenatal care late in pregnancy. In most cases a further 2 - 4 weeks will elapse before the second antenatal visit. Appropriate management in the event of maternal syphilis is therefore delayed in every patient. This may prove fatal for the baby. Under these circumstances it becomes mandatory to diagnose maternal syphilis and initiate treatment at the time pregnancy is diagnosed in order effectively to prevent congenital syphilis.[1]

The objectives of the study were to determine the sensitivity, specificity, negative predictive value and positive predictive value of the rapid plasma reagin (RPR) test as performed on site in an antenatal clinic with no sophisticated equipment.

Patients and methods

All patients attending the antenatal clinic at Kalafong Hospital, Pretoria, for the first time were included in the study. Two specimens of blood were obtained from each patient. One specimen was dispatched to the laboratory for serological tests for syphilis (STS), and the other specimen was used to perform the RPR test at the clinic. A registered nurse, who acted as a research assistant for the purpose of the study, performed the test. This had been demonstrated to her in a teaching session which lasted 15 minutes. No controls were used during the on-site testing because all results were verified by results from the laboratory. Dispenstirs, RPR cards and carbon antigen were supplied by Bactlab, Johnson & Johnson and Davies Diagnostics, respectively. The method used in the clinic was similar to that used in the laboratory with the following exceptions:

1. Manual rotation of the card to mix the antigen and serum replaced a mechanical rotator.

2. In the event of macroscopic flocculation, no serial dilutions were performed in the clinic. Results were reported as negative, weakly positive or strongly positive. The latter are characterised by definite macroscopic flocculation. Since a centrifuge was available at the clinic it was used to obtain serum. The RPR test can, however, be performed on plasma. This is obtained by collecting blood in an ethylenediamine tetra-acetic acid

Department of Paediatrics, Kalafong Hospital and University of Pretoria

S. D. DELPORT, M.MED (PAED.), M. PHARM. MED.

Accepted 24 Nov 1992.

(EDTA) tube after which the red blood cells are allowed to sediment down. Approximately 1 hour is needed to obtain plasma in this way.

The results of the RPR test were reported by the laboratory as negative or in titres of 1:8 up to 1:1 024. Titres of 1:1, 1:2, and 1:4 were reported as negative, in keeping with the present policy. The *Treponema pallidum* haemagglutination (TPHA) test was performed in the laboratory in addition to the RPR test to exclude a false-positive RPR result. The results of the RPR test performed in the clinic were compared with the results of the RPR test reported by the reference laboratory for sensitivity, specificity, negative and positive predictive values. The cost of the RPR test as performed on site was determined by costing of the consumables and labour required.

If the RPR test was strongly positive on site, patients were counselled and received an injection of benzathine penicillin G 2 400 000 units intramuscularly. They were asked to return a week later for confirmation of the result and further treatment if indicated. Letters to consorts were issued to patients in the event of confirmed positive results, and they were requested to attend a clinic for sexually transmitted diseases. In the event of a weakly positive test, the patient was requested to return a week later for results of the detailed STS from the laboratory.

Results

A total of 1 237 patients was screened over a 7-month period (1 August 1991 to 29 February 1992). Results from the laboratory showed that 83 patients (6,7%) had RPR titres of 1:8 or more (Fig. 1). All patients had a positive TPHA test as well. The clinic identified 77 of these patients by performing the RPR test on site and finding it to be strongly positive. The remaining 6 patients who were not identified in the clinic all had low RPR titres of 1:8 as reported by the laboratory. The sensitivity of the RPR test performed on site was 92,8% and the negative predictive value was 99,5%. The specificity was 96,3% and the positive predictive value 64,7%. The low positive predictive value is ascribed to a learning curve during the first month of the study when a definite distinction was not made in the reporting of weakly reactive and strongly reactive flocculation tests. The positive predictive value increased from 44,1% in the first month to 78,6% in the last month of the study.

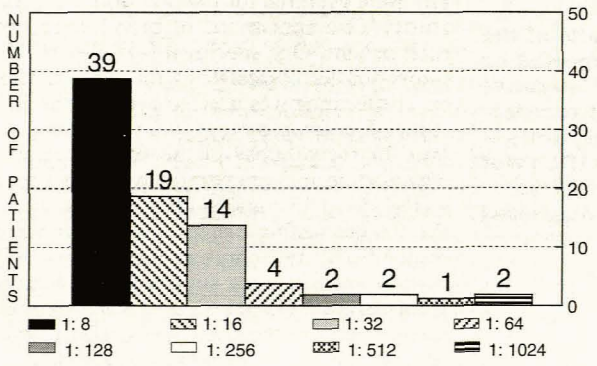

FIG. 1.
Distribution of reagin titres.

Approximately 2 minutes are required to perform a RPR test in an antenatal clinic if 10 tests are done simultaneously. No sophisticated equipment is necessary if the RPR test is performed on plasma obtained after the red blood cells have been allowed to sediment down. The cost of consumables per test was 23 cents. The labour required to perform the test was priced, and found to be 7 cents per test. The total cost per test was therefore 30 cents. The cost to screen 1 237 patients in order to identify 92,8% of diseased individuals was R371,10.

Discussion

The results of this study show that maternal syphilis can, in the majority of cases, be diagnosed by a nurse during the first visit to an antenatal clinic by using an RPR test, which is performed at minimal expense and without sophisticated equipment. In populations who seek antenatal care late in pregnancy and whose return rate may be low, a diagnosis of maternal syphilis on site becomes essential.[1] In the absence of clinical signs the diagnosis depends exclusively on the results of the STS.

All cases in need of treatment will, however, not be identified because of the following shortcomings of STS:

1. Primary infections that are acquired late in pregnancy may not be detected serologically. These women may be asymptomatic and spirochaetaemia may precede seroconversion.[2]

2. Reactive non-treponemal test titres of less than 1:8 may be present in the primary or latent stages of the disease and be interpreted as negative.

3. False-positive RPR results occur with low titres, but these are seen in populations with a low prevalence of the disease.[3] They are readily identified by means of a negative treponemal test.

4. False-negative RPR tests may occur during active disease as a result of the prozone phenomenon. The latter occurs when there is an excess of antibody in the serum to such an extent that the formation of the antibody-antigen lattice network required for flocculation is prevented. Dilution of the serum re-establishes the proper concentrations of antibody and antigen which will then result in a positive test result.[4]

5. Treponemal (e.g. TPHA) tests, although more specific in the primary stage of syphilis,[5] are serofast, yielding positive results for years after successful treatment. They cannot be used to assess the current state of activity of infection.

The RPR test, although lacking specificity, remains invaluable as a screening test. Our results show that effective screening can take place on site. These tests, when reported as titres, also enable the clinician to assess the degree of activity of disease and the response to treatment. Complete commercial kits are available at a cost of 46c per test.

In view of the high negative predictive value of the RPR test, it is recommended that a negative test performed on site does not need to be repeated in the laboratory. A strongly positive RPR test on site should be followed by immediate treatment and detailed STS performed in a laboratory to quantitate the titre. Patients with weakly positive RPR test results on site should not receive treatment, but be asked to return a week later for results of detailed STS.

I thank Sister Sarah Thabethe for her unfailing assistance and Professor J. V. van der Merwe for granting me a research assistant for the purpose of the study.

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