Detection of Endocervical Anti-Chlamydia trachomatis Immunoglobulin A in Pregnant Women by a Rapid, 6-Minute Enzyme-Linked Immunosorbent Assay: Comparison with PCR and Chlamydial Antigen Detection Methods

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Chlamydia trachomatis, a prevalent sexually transmitted bacterial pathogen, is associated with infertility due to fallopian tube occlusion (4), ectopic pregnancy (4), and adverse pregnancy outcome (9, 11, 16, 17). In the majority of women infected by this organism, symptoms are minimal or nonexistent (4). Therefore, screening of women at risk for chlamydial infection has been advocated (5, 12, 14).

There is a need for a rapid, uncomplicated, and inexpensive test for Chlamydia trachomatis infection in women. We evaluated the ability of a 6-min enzyme-linked immunosorbent assay (ELISA) that requires no laboratory equipment (IgA Rapid SeroTest; Savyon Diagnostics) to detect C. trachomatis immunoglobulin A (IgA) in the endocervices of 167 inner-city pregnant women and compared the results with DNA amplification (Amplior PCR; Roche Diagnostics) and antigen detection (Chlamydiurate; Abbott Laboratories) performed on the same women. Anti-C. trachomatis IgA was detected in the cervices of 32 women (19.2%). Samples from 23 women (13.8%) were PCR positive, while chlamydial antigen was present in 20 women (12.0%). There was only 1 sample (4.3%) that was positive by PCR but negative by ELISA; 10 samples were ELISA positive and PCR negative. In contrast, seven samples (30.4%) were PCR positive but Chlamydiurate negative and four were Chlamydiurate positive and PCR negative. Compared to PCR, the IgA ELISA had a sensitivity of 95.7%, a specificity of 93.1%, a positive predictive value of 68.8%, and a negative predictive value of 99.3%. The antigen assay had a sensitivity of only 69.6%, a specificity of 97.2%, a positive predictive value of 80.0%, and a negative predictive value of 95.2%. In high-risk groups where laboratory testing is not available, or where the patient might not return to obtain her testing result and be treated, the Rapid IgA SeroTest is a viable alternative for detection of cervical C. trachomatis in pregnant women.

The value of anti-C. trachomatis endocervical immunoglobulin A (IgA) antibody determination for diagnosis of a current infection remains controversial. McComb et al., using a detection assay that did not differentiate between IgA and IgG antibodies, demonstrated that the presence of antichlamydial immunoglobulins in the cervix, but not in the circulation, correlated with chlamydial isolation from the cervix (8). Brunham et al. also reported that cervical antichlamydial immunoglobulin was more specific than serum antibody in detecting a culture-positive infection (3). In contrast, a third study did not find cervical antibodies useful in the diagnosis of a C. trachomatis infection in a low-prevalence population (13).

In the present study, we evaluated the ability of a rapid enzyme-linked immunosorbent assay (ELISA) for cervical antichlamydial IgA to detect PCR-positive C. trachomatis endocervical infections in inner-city pregnant women.

MATERIALS AND METHODS

Subjects. Testing was performed on 167 pregnant women seen at the Jersey City Medical Center. The racial composition was 48.8% Hispanic, 37.8% black, 7.3% Caucasian, and 6.1% Asian. Mean ages were 24.3 (Hispanic), 24.0 (black), 29.2 (Caucasian), and 27.4 (Asian) years. Most (>95%) were unmarried and receiving public assistance. Subsequent pregnancy outcome data was not available.

Sample collection. Three samples were collected from each pregnant woman by inserting Dacron swabs into the endocervix and rotating the swabs 360° prior to removal. In random order, one swab was placed in an Amplior collection tube (Roche Diagnostics, Totowa, N.J.) for PCR analysis, a second swab was placed in Chlamydiurate storage reagent (Abbott Laboratories, North Chicago, Ill.), and sent to the clinical microbiology laboratory for chlamydial antigen detection, and the third swab was placed in 0.5 ml of phosphate-buffered saline (PBS), the liquid was extracted from the swab with a Pasteur pipette, the sample was microcentrifuged, and the supernatant was frozen at −80°C until tested for antichlamydial IgA.
**RESULTS**

*C. trachomatis* DNA was detected by PCR in the endocervical samples of 23 (13.8%) of the pregnant women tested. Chlamydial antigen was detected in cervical swabs from 20 (12.0%) of the women, while 32 (19.2%) were positive for antichlamydial cervical IgA. There was no relation between race and chlamydial prevalence by any of the assays.

Repeat analyses of discordant results were performed. To rule out the presence of PCR inhibitors in samples that were negative by PCR for *Chlamydia* cryptic plasmid DNA but positive in the antigen or antibody assays, purified *C. trachomatis* was added to aliquots of each sample and this PCR was repeated. In each case, chlamydial DNA was readily detected by the Amplicor assay. Other aliquots were tested by PCR with primer pairs specific for a region of the chlamydial major outer membrane protein (MOMP) gene. Each of the antigen- or antibody-positive samples that were previously PCR negative remained negative for the presence of the MOMP gene. Repeat analyses by each of the assays in PCR-positive but antigen- or antibody-negative samples confirmed the original findings.

Only 1 woman of 23 (4.3%) was positive by PCR but lacked detectable IgA antibodies. This was significantly less (*P* = 0.04) than the seven women (30.4%) who were positive by PCR but negative for detectable chlamydial antigen.

There were 10 women who were positive for antichlamydial IgA but negative by PCR and by antigen assay. Similarly, four women were positive only in the chlamydial antigen detection assay. Relative to PCR, the IgA assay had a sensitivity of 95.7%, a specificity of 93.1%, a positive predictive value of 68.8%, and a negative predictive value of 99.3%. The antigen assay had a sensitivity of 69.6%, a specificity of 97.2%, a positive predictive value of 80.0%, and a negative predictive value of 95.2% (Table 1).

**DISCUSSION**

The IgA Rapid SeroTest detected endocervical *C. trachomatis* infections in 22 of 23 (95.7%) pregnant women whose infections were identified by PCR. This was a higher percentage than the number of PCR-positive women who could be identified by a *Chlamydia* antigen-based assay. Thus, in the absence of even the most basic laboratory facilities, *C. trachomatis* could be detected with high sensitivity by this qualitative cervical IgA ELISA. This assay, however, had a positive predictive value of only 68.8%, indicating that some women with no evidence of endocervical chlamydial DNA will, nevertheless, be scored as harboring this organism.

In the 10 women positive for antichlamydial IgA but negative for chlamydial DNA, the possible presence of PCR inhibitors in the samples was ruled out. Alternative explanations for this finding are that (i) there was a recently cleared chlamydial infection in these women and the IgA immune response had not yet subsided, (ii) there was a chlamydial infection above the level of the endocervix that, nevertheless, induced a cervical immune response, or (iii) although none of the cervical samples was visibly contaminated with blood, the possible presence of occult blood contamination in women previously exposed to *C. trachomatis* or to another chlamydial species could lead to a positive cervical antibody test. *Chlamydia* antibody ELISA tests are genus specific, not species specific, and so women infected with *C. pneumoniae* or *C. psittaci* and who have antibodies to these organisms circulating may be scored as false positives in *C. trachomatis* antibody testing (10). At present we cannot differentiate between these alternatives. Sera from these women were not available for analysis.

The IgA Rapid SeroTest appeared to offer a convenient and sensitive means to test for *C. trachomatis* in nonlaboratory settings (i) in women in high-prevalence risk groups who may not be available for treatment at a later date if their *C. trachomatis* testing is positive or (ii) in situations where laboratory testing is not available. However, treatment based solely on the antibody findings, although likely to identify those women with PCR-positive infections, may result in unnecessary antibiotic usage in some cases.

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**REFERENCES**


