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Feasibility of *Chlamydia trachomatis* screening and treatment in low-risk pregnant women in Lima, Peru: a prospective study in two large urban hospitals

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Abstract

Objectives—*Chlamydia trachomatis*, which is asymptomatic in most women, causes significant adverse effects for pregnant women and neonates. No programmes conduct antenatal screening in Latin America. We determined chlamydi*a* prevalence, the feasibility and acceptability of chlamydi*a* screening, and adherence to treatment in pregnant women in two urban public hospitals in Lima, Peru.

Methods—We offered chlamydia screening using self-collected vaginal swabs to pregnant women ≥ 16 years during their first antenatal visit. Chlamydia-infected women were contacted within 14 days and asked to bring partners for counselling and directly observed therapy with oral azithromycin. Unaccompanied women received counselling, directly observed therapy, and azithromycin to take to partners. Test of cure was performed ≥ 3 weeks after treatment.

Results—We approached 640 women for the study and enrolled 600 (93.7%). Median age was 27.3 years (range 16–47), median lifetime partners 2.3 (range 1–50), and median gestational age 26.1 weeks (range 4–41). Chlamydia prevalence was 10% (95% CI: 7.7% – 12.7%). Of 60 infected patients, 59 (98%) were treated with one dose of azithromycin. Fifty-two of 59 (88%)

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returned for test of cure, all of whom were treated successfully, with 46 (86%) achieving negative test of cure with one dose of azithromycin and 6 (12%) after retreatment with a second dose.

Conclusions—*C. trachomatis* screening and treatment in pregnancy was feasible and highly acceptable in two urban hospitals in Peru. Chlamydia prevalence was high. Clinical trials to evaluate efficacy and cost-effectiveness of chlamydia screening and treatment of pregnant women to prevent adverse pregnancy outcomes in low-resource settings are warranted.

Keywords

Chlamydia; pregnancy; screening

Chlamydia trachomatis, the most common sexually transmitted bacterial infection worldwide, causes significant adverse outcomes in pregnancy, including preterm birth, low birth weight, premature rupture of membranes, stillbirth, and miscarriage, as well as inclusion conjunctivitis and pneumonia in neonates (1). No programmes routinely conduct *C. trachomatis* screening in antenatal care in Latin America, and there are no World Health Organization recommendations for routine *C trachomatis* screening and treatment in pregnant women. To prepare for a trial of *C. trachomatis* screening and treatment in pregnancy to reduce adverse pregnancy outcomes, we explored the feasibility and acceptability of *C. trachomatis* screening in pregnant women during the first antenatal visit and determined *C. trachomatis* prevalence and patient and partner treatment outcomes to treatment in Lima, Peru.

METHODS

Study Design

We conducted a prospective study in two large urban hospitals in Lima, Peru: Instituto Nacional Materno Perinatal (INMP) and Hospital Nacional Arzobispo Loayza (HNAL). INMP participants were recruited in January 2013; HNAL participants were recruited December 2012 – January 2013.

During the recruitment period, all pregnant women attending their first antenatal visit were given a brief explanation by hospital midwives about risks of chlamydia infection during pregnancy and were told about the study. We focused on the first antenatal visit since women routinely have antenatal counselling and HIV / syphilis screening at this time. Women ≥ 16 years old who were interested in participating were screened for eligibility by research midwives and enrolled after providing informed consent. Consecutive women were recruited at the HNAL. Even-numbered women were recruited at the INMP (odd- numbered patients were recruited by another concurrently running research study). Women not mentally competent to understand informed consent were excluded; minors were required to have consent from parent or guardian to participate. The study protocol was approved by the institutional review or ethical boards at the University of California, Los Angeles Universidad Peruana Cayetano Heredia, and each participating hospital.

Women provided self-collected vaginal swabs for chlamydial testing after being instructed on collection technique by the study midwife, and then completed a face-to-face

questionnaire regarding demographic data, reproductive and medical history, and number of sexual partners.

Women who tested positive for chlamydial infection were asked to return to the hospital for counselling and directly observed treatment with 1 gram of oral azithromycin. They were given the option of bringing their partner(s) with them for counselling and directly observed concurrent treatment at the hospital or of delivering 1 gram azithromycin to the partner at home. About 3 weeks after treatment, infected women were contacted to provide a second self-collected vaginal specimen to perform a test of cure to document clearance of infection.

Testing was free, and we reimbursed women their transportation costs to return for treatment and for test of cure.

Laboratory

Specimens were tested for *C. trachomatis* infection using the Aptima Combo2 system (Hologic, Gen Probe Incorporated, San Diego, CA) at the Universidad Peruana Cayetano Heredia Laboratory of Sexual Health in Lima, Peru.

Data management and statistical analysis

Screening acceptability and *C. trachomatis* prevalence were calculated with 95% confidence intervals. To test the association between categorical variables and *C. trachomatis* positivity, we used either Chi-squared or Fisher's exact tests. All other numerical variables were assessed using the Mann-Whitney test. Individuals with missing data were excluded only from the affected analysis. We conducted all analysis using Stata 12.1 (Stata Corporation, College Station, Tx).

RESULTS

Participation rate

Of 640 pregnant women during the recruitment period who heard presentations regarding the study, 3 were excluded (high risk pregnancy, unaccompanied minor, or no intention to return to hospital). Of the remaining 637 eligible women, 600 (93.8%) enrolled: 333 (55.5%) from INMP and 267 (44.5%) from HNAL. The most common reasons given for not participating were lack of time (n=15), fear of being tested (n= 7), and not considering the study important (n=7). Five women did not give any reason, and three wanted to consult with family/friends before enrolling but never enrolled.

Participant characteristics

Table 1 shows participant characteristics.

C. trachomatis prevalence

C. trachomatis was identified in 60 study participants (10%; 95% CI: 7.7% – 12.7%). Prevalence decreased with age; the youngest women (16–23 years) had the highest prevalence (15.6%), and older women (≥ 31 years) had the lowest (5.2%). Prevalence was

higher for single women than for women who were married or cohabiting, but was unrelated to lifetime number of sex partners, education level, or current vaginal symptoms.

Treatment

Of the 60 *C. trachomatis*-positive patients, 59 (98.3%) received treatment. Fifty-five of 59 partners (93%) received treatment, 21 of them (36%) at the hospital, concurrently with the women, and 34 (58%) with medication brought home by the women.

Fifty-two (91%) treated women returned for test of cure. Forty-six tested negative (infection cured). Of the six who tested positive, indicating continuing infection, three had received concurrent therapy with their partners, two had brought treatment home, and one denied partner contact after treatment. All six were retreated, and subsequent tests of cure were negative.

DISCUSSION

Chlamydial screening in pregnant women at two large urban hospitals in Lima was feasible and highly acceptable. All women who tested positive for chlamydia and returned for treatment and test of cure were successfully treated.

Our data regarding prevalence were consistent with previous research in Peru and globally, showing that the youngest women are most likely to be infected (1,2). It is worth noting that in our study, prevalence was also high (5.1%) among women ≥ 31 years, an age category not generally included in screening programs.

The participation rate for screening with self-administered vaginal swabs was high (93.8%) which is consistent with previous studies in high-income countries (3). Self-administered vaginal swabs with nucleic acid amplification testing is a non-invasive diagnostic method that has sensitivity and specificity equivalent to provider-collected samples (4), an advantage in resource limited settings where there may be health personnel shortages. In addition, vaginal swabs are easier to transport and are equally or more sensitive and specific for diagnosis of chlamydial infection than urine samples (4).

One potential disadvantage of such molecular-based testing is the absence of laboratory testing capacity in low and middle income settings, although with the advent of HIV/AIDS RNA testing and the widespread introduction of molecular testing for tuberculosis in low and middle income settings, that capacity is rapidly increasing (5). Since results are not, available at point-of-care, another drawback of such testing is potential loss to follow up, but as yet there exists no point-of-care testing with adequate sensitivity and specificity for screening (6).

C. trachomatis positivity at test of cure was 12%, similar to levels in previous studies of recurrent or persistent infections for women treated for genital chlamydia (7). No significant resistance of *C. trachomatis* to azithromycin has been reported in the literature, but pharmacologic treatment failure, defined as persistent infection despite antibiotic use, may result from variations in drug absorption, metabolism, or host immune response (8). False positive results in the test of cure may occur from persistence of residual DNA from non-

viable chlamydia (3). To avoid this problem, current treatment guidelines recommend waiting at least 3 weeks before repeating nucleic acid amplification testing (3), although residual DNA may persist for longer periods (9).

Although women were encouraged to bring partners to the hospital for treatment and counselling, nearly 60% chose to bring medication home to partners. This practice, known as patient-delivered partner therapy, is recommended by the US Centers for Disease Control as an alternative therapy for certain sexually transmitted diseases. This is an important consideration, since several studies in developing countries suggest that reliance on patient referral of partners for therapy is often ineffective (10). More research is needed on the use of patient-delivered partner therapy for partner treatment in low-resource settings.

Our study had several limitations. Women were recruited only from large public hospitals in Lima, so results might not be generalizable to other settings, such as rural areas and mid-sized cities. The educational level in our sample is somewhat higher than average for metropolitan Lima, and since we have no demographic data on the women who chose not to participate, we cannot rule out the possibility that there may have been a selection bias such that women who are more educated were more likely to participate in the study. Despite these limitations, however, we believe that because our study was carried out in two national hospitals with large antenatal services, and because most women in Lima give birth in hospitals, our prevalence estimates, treatment acceptability, and risk factors are similar to those for the larger population of low-risk pregnant women in Lima.

C. trachomatis screening in pregnancy was feasible and acceptable in two large urban maternity hospitals in Lima, Peru. Partner treatment was also readily accepted. The prevalence of *C. trachomatis* infection was high. Given the strong associations between *C. trachomatis* in pregnancy and adverse pregnancy outcomes, a clinical trial to demonstrate the efficacy and cost-effectiveness of *C. trachomatis* screening and treatment in low and middle income countries is urgently needed.

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Key Messages

- *Chlamydia trachomatis* screening and treatment in pregnancy was feasible and highly acceptable in two urban hospitals in Peru.
- *Chlamydia trachomatis* prevalence was high in this setting.
- Clinical trials to evaluate the efficacy and cost-effectiveness of *Chlamydia trachomatis* screening and treatment in pregnant women to prevent adverse pregnancy outcomes in low resource settings are warranted.

Table 1

Characteristics of the study participants, total and stratified by CT lab result (N=600)

		Result for Chlamydia tests		
	Total sample (N=600)	**Positive (N=60)**	**Negative (N=540)**	**p value*****
Characteristic	**N (%)**	**N (%)**	**N (%)**	
Age in years	27 (21–32)*	23 (20–38)	27 (22–33)	<0.05
Age categorized				
1st tertile (16–23)	212 (35.3)	33 (15.6)	179 (84.4)	<0.05
2nd tertile (24–30)	196 (32.7)	17 (8.7)	179 (91.3)	
3rd tertile (31–47)	192 (32.0)	10 (5.2)	182 (94.8)	
Education				
None/Elementary	26 (4.3)	4 (15.4)	22 (84.6)	0.58
Some High School	363 (60.5)	37 (10.2)	326 (89.8)	
Some University/Tech	211 (35.2)	19 (9.0)	192 (91.0)	
Partnership status				
Single/Separated/Widowed	116 (19.3)	20 (17.2)	96 (82.8)	<0.05
Married/Cohabitating	484 (80.7)	40 (8.3)	444 (91.7)	
Parity				
First Pregnancy	218 (36.3)	27 (12.4)	191 (87.6)	0.14
> Second Pregnancy	382 (63.7)	33 (8.6)	349 (91.4)	
Gestational age in weeks				
First trimester (1 – 12)	94 (15.7)	11 (11.7)	83 (88.3)	0.60
Second trimester (13 – 27)	182 (30.3)	15 (8.2)	167 (91.8)	
Third trimester (28 and over)	324 (54.0)	34 (10.5)	290 (89.5)	
Sexual History				
Age at first intercourse	18 (16–19)*	17 (16–19)	18 (16–19)	0.10
Lifetime no. partners	2 (1–3)*	2 (1–3)	2 (1.3)	0.66
Prior diagnosis of syphilis	9 (1.5)	0 (0.0)	9 (100.0)	0.10
Prior diagnosis of HIV	3 (0.5)	0 (0.0)	3 (100.0)	0.07
Condom use in last encounter	30 (5.0)	3 (10.0)	27 (90.0)	0.95
STD symptoms (current)**				
Vaginal discharge	524 (87.3)	52 (9.9)	472 (90.1)	0.87
Genital wart	36 (6.0)	3 (8.3)	33 (91.7)	0.69
Genital ulcer	26 (4.3)	2 (7.7)	24 (92.3)	0.73
None	71 (11.8)	8 (11.3)	63 (88.7)	0.95
Positive for CT (test used in study)	60 (10.0)	60 (100.0)	0 (0.0)	NA
Positive for syphilis (chart review)	8 (1.3)	0 (0.0)	8 (100.0)	0.18
Positive for HIV (chart review)	3 (0.5)	0 (0.0)	3 (100.0)	0.69

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* Median (IQR)

** could report more than 1 concurrent symptom

*** Chi square test except for numeric variables marked with "*" where Mann-Whitney test was used.

NA=Not applicable

For the total sample column, percentages are displayed along the column

For the stratified analysis, percentages are displayed along the row