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Validity of Self-Reported History of *Chlamydia trachomatis* Infection

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Abstract

Background: *Chlamydia trachomatis* (CT) infection is common and largely asymptomatic in women. If untreated it can lead to sequelae such as pelvic inflammatory disease and infertility. It is unknown if a patient's self-reported history of CT infection is a valid marker of past infection.

Objective: Our objective was to evaluate the validity of women's self-reported history of CT infection compared to CT serology, a marker for previous infection.

Study Design: We analyzed data from the Fertility After Contraception study. We compared participants' survey responses to the question, "Have you ever been told by a healthcare provider that you had Chlamydia?" to serological test results indicating the presence or absence of antibodies to CT as assessed by microimmunofluorescence (MIF) assay. Prevalence of past

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infection, sensitivity, specificity, predictive values, and likelihood ratios were calculated. Cohen's kappa statistic was computed to assess agreement between self-report and serology.

Results: Among 409 participants, 108 (26%) reported having a history of CT infection, whereas 146 (36%) had positive serological test results. Relative to positive MIF assay, the sensitivity and specificity of self-reported history of CT infection were 52.1% (95% CI, 43.6%, 60.4%) and 87.8% (95% CI, 83.3%, 91.5%), respectively. Positive predictive value of self-report was 70.4% (95% CI, 60.8%, 78.8%), and the negative predictive value was 76.7% (95% CI, 71.6%, 81.4%). The likelihood ratio was found to be 4.28. Agreement between self-report and serology was found to be moderate (kappa = 0.42, $P < 0.001$).

Conclusion: Self-reported history of CT infection commonly yields false negative and false positive results. When definitive status of past CT infection is needed, serology should be obtained.

Condensation:

Self-reported history of *Chlamydia trachomatis* infection has limited validity as a measure of a patient's past exposure to chlamydial infection.

Keywords

Chlamydia trachomatis; microimmunofluorescence assay; self-report; serology; sexually transmitted infection; validity

INTRODUCTION

Chlamydia trachomatis (CT) infection is the most common notifiable sexually transmitted infection (STI) in the United States and is largely asymptomatic. Up to 80% of women with CT infections experience no symptoms.[1,2] If CT infections are not diagnosed and treated in a timely manner, these infections can progress and lead to pelvic inflammatory disease (PID), chronic pelvic pain, and infertility. Healthcare providers may ask about previous CT infection while taking a medical history, but it is unclear to what degree a self-reported history of CT infection is a valid measure of past infection.

Although the literature contains several studies assessing the validity of self-reported STIs, few studies specifically evaluate the validity of self-reported CT infection.[3,4] One randomized controlled trial for a STI intervention program found that only 68% of African-American, female teenagers with a laboratory confirmed CT infection correctly reported their history of infection one month after learning of their diagnosis.[5] A study performed by Niccolai et al. compared female adolescents' self-reported CT diagnoses to a composite reference standard defined as positive if either the participant's medical record or a state health department report showed the patient to have a history of CT infection. This study found a high specificity of 97.3% and a sensitivity of 69.1%.[6]

The purpose of this analysis is to evaluate the validity of women's self-reported history of CT infection compared to CT serology as assessed by microimmunofluorescence (MIF), a sensitive marker for previous infection with CT.[7] Self report and serology may not agree for

many reasons, including lack of understanding of test results, desire to not disclose a history of positive test results, and the absence of prior testing, either due to the asymptomatic nature of the infection or lack of access to testing. Given all these complexities surrounding self-reported history of CT infections, we hypothesize that women will significantly underestimate their history of past infection and that a reported history of CT infection is not a reliable marker of past infection.

MATERIALS AND METHODS

We performed a cross-sectional analysis of the Fertility After Contraception Termination (FACT) study. FACT is a prospective cohort study developed primarily to assess the role of infection and contraceptive use (specifically intrauterine device (IUD) use) on fertility. We compared self-reported CT infection to serologic results obtained at the time of baseline interview and evaluation.

Many of the FACT participants were recruited from the Contraceptive CHOICE Project, a prospective cohort study of 9,256 women in the St. Louis area who were provided with no-cost contraception for 2–3 years. A more in-depth methodological description of the CHOICE project has been previously described.[8] We augmented our sample size with recruitment from four additional clinical research programs (University of Pennsylvania, University of Colorado, University of Utah, and University of Southern California). Institutional review boards at all participating institutions approved this study, and written informed consent was obtained from all participants prior to study involvement.

English- or Spanish-speaking women between the ages of 18 to 35 were eligible for the study if they were discontinuing a contraceptive method to attempt pregnancy. Women were excluded if they met the following criteria: (1) were pregnant at time of enrollment; (2) did not have a male partner at time of enrollment; (3) were going to be physically separated from their male partner for six months or longer; (4) were with a male partner who has a history of vasectomy, infertility, or abnormal semen analysis; (5) had a history of infertility, tubal reconstructive surgery, or sterilization; or (6) had medical problems known to affect fertility (e.g., cancer therapy, thyroid problems, Cushing's disease, sickle cell disease, kidney disease, and diabetes).

Baseline investigations included a questionnaire, a clinical exam, blood samples for serologic testing for CT, *Mycoplasma genitalium* (MG), and *Trichomonas vaginalis* (TV), and nucleic acid amplification testing (NAAT, APTIMA, Gen-Probe) for current STIs (*Neisseria gonorrhoeae*, CT, TV, and MG). Although both serology and nucleic acid amplification testing were available for CT, MG, and TV, we decided to focus our study on CT given that it is the most common nationally notifiable sexually transmitted disease and it is likely a more well-known STI compared to MG or TV. Baseline data collection included demographic, historical, medical/surgical history, and reproductive characteristics. As part of the baseline questionnaire, participants were asked if they have ever been told by a healthcare provider that they had chlamydia. Participants' "yes" or "no" answers to this question represented their self-reported history of CT infection.

The serological samples taken at baseline were used to assess current and/or previous CT infection. The samples were clarified by centrifugation, aliquotted, and frozen at −80°C. Samples were then transported on dry ice to the University of Washington Chlamydia Laboratory for analysis using the microimmunofluorescence assay developed by Wang et al. as modified by Hanna and Keshishyan.[9,10] All serologic assays were performed by the same experienced technician. Based on a previous receiver operating characteristic curve analysis of CT antibody titers and laparoscopically-confirmed tuboperitoneal abnormalities, we considered a titer of 1:16 as evidence of a positive history of CT infection.[11] While previous studies have used cutoff dilutions ranging from 1:8 to 1:640, not all used the same technique or staff to perform this technically complicated assay.[12]

Only those participants whose serologic results were returned by the time of analysis were included. Dates of data collection for this analysis ranged from September 8, 2011 to February 25, 2016. Baseline demographic characteristics of this sample were compared using chi-square, Fisher exact, and Student's t–tests, as appropriate. Prevalence of past infection was calculated using the serological data. Sensitivity, specificity, predictive values, and positive likelihood ratio for self-reported history of infection were also calculated. Cohen's kappa statistic was calculated to assess agreement between self-report and serology. Bivariate logistic regression analysis was performed to assess the association between the baseline demographic characteristics and self-reported CT history and serologic CT results. All statistical analyses were performed using SAS 9.4 software. The significance level of alpha was set at 0.05.

RESULTS

At the time of data analysis, 440 women had enrolled in FACT. A total of 432 participants responded to the question "Have you ever been told by a healthcare provider that you had chlamydia", and 420 had serologic data available. Four hundred and nine participants had both data points available and are included in our data analysis.

The baseline demographic, reproductive, and behavioral characteristics by self-reported history of CT infection and serologic status are provided in Table 1. The mean age of participants was 28 years. Forty-two percent of participants were black, 8% reported Hispanic ethnicity, 57% were married, 22% had a high school education or less, 38% were of low socioeconomic status, 36% smoked, 14% used drugs, and 24% had no insurance. Seventeen participants (4.2%) had positive CT test results at the baseline encounter. Participants with a positive self-reported or serologically confirmed history of CT were more likely to be younger, higher gravidity, non-white, unmarried, of lower educational level and SES, former implant or depo-medroxyprogesterone acetate (DMPA) users, uninsured, and a current drug user.

Table 2 compares self reported CT infection to serologic status. Twenty-six percent of participants reported having a history of CT infection whereas 36% of participants had positive serological test results. . Of the 146 women who had antibodies to CT, 76 reported a history of CT infection. Conversely, of the 263 women who had no antibodies to CT, 231 reported never having a CT infection in the past. The sensitivity and specificity of women's

self-reported history of CT infection were 52.1% (95% confidence interval (CI), 43.6%, 60.4%) and 87.8% (95% CI, 83.3%, 91.5%), respectively. Positive predictive value of self-report was 70.4% (95% CI, 60.8%, 78.8%), and the negative predictive value was 76.7% (95% CI, 71.6%, 81.4%). The positive likelihood ratio was found to be 4.28. The agreement between self-reported history of CT infection and serological testing was calculated using Cohen's kappa statistic. The tests show moderate agreement (kappa = 0.42, $P < 0.001$).

The results of our multivariable logistic regression model of predictors of self-reported CT history and positive CT serology are shown in Table 3. Young age, non-white race, unmarried marital status, lower education and SES, implant use, non-private insurance, poorer health, current drug use, and young age at first pregnancy were associated with both self-reported history of CT and serologic positivity.

COMMENT

Self-report is an affordable and convenient way to assess a patient's history of CT infection, yet few studies have examined its validity. When evaluating validity of self-report in women enrolled in the FACT study, we found self-report to not be a valid marker of past CT infection status. Only 52% of women with positive serology reported a history of CT infection. This low sensitivity indicates a high false negative rate. Specificity was higher at 88%, indicating a false positive rate of 12%. Our positive and negative predictive values of self reported CT infection were 70% and 77%, respectively. Thus, 30% of participants who reported a history of CT infection did not have a history of infection according to serology, and almost 25% of participants who reported not having a history of CT infection actually had serologic evidence of infection. In addition, the likelihood ratio of 4.28 only shows a moderate increase in the likelihood of past disease given positive self-report. The Cohen's Kappa of 0.4 indicates a moderate level of agreement between self-report and serology.[13]

There are several explanations as to why women would report no history of CT infection in the setting of positive serology. Since most CT infections are asymptomatic, it is possible that these women never sought out testing or were not appropriately screened per current guidelines.[14] Even if participants were symptomatic, they may not have sought or received testing. It is also possible that participants who have received CT testing in the past did not receive, remember, or understand the results of this testing. Lastly, participants may have decided not to disclose their history of CT infection.

There are several reasons why participants may have reported a history of CT infection in the setting of negative serology. Studies have shown that women have many misconceptions regarding STI testing. One study found that 32% of participants thought visual inspection by a provider was a valid method to screen for CT infection, and 26% believed that Papanicolaou tests screen for CT infection.[15] In this context, it is possible that some participants misunderstood what reproductive health testing they received in the past and/or the results of those tests. It is also possible that some participants may have mistaken an alternative STI diagnosis as CT.

This study found a surprising association between self-reported and serologically confirmed CT infection and contraceptive implant use. It is possible that this association is mediated by age. The contraceptive implant is a popular choice of birth control among young women and young women below the age of 24 are at highest risk for CT infection.[16,17] It is unlikely that this association is due to changes in sexual activity among women who use the contraceptive implant.[18]

Our study has several strengths. First, the broad age range of participants, 18 to 35 years of age, and the geographic distribution of participants adds to the generalizibility of our findings. Second, our use of serology as a marker of past infection is a major strength. The microimmunofluorescence assay is a sensitive assay for past infection as antibodies to CT may persist for many years even after antibiotic treatment.[19–21] It also requires a high degree of technical skill, and all of the assays in this study were performed by a single technician with decades of experience in this technique. Third, our study population includes women who may not have been previously tested for CT infection. This differs from the study populations in the available literature. Participants in the Harrington et al study were tested for CT, informed of their results, and later asked to recall these results.[5] The Niccolai study used a composite reference standard defined as positive if either the participant's medical record or a state health department report showed the patient to have a history of CT infection.[6] This choice of reference standard limits the participants to those who have been tested for CT as participants without any records were excluded from analysis. Therefore our study population may be more generalizable as healthcare providers cannot assume ubiquitous testing in a majority of clinical populations in the United States.

Limitations of the current study include our use of a 1:16 cutoff to define positive serology. Our decision to use this cutoff is well supported by the literature and our experience with this assay in the laboratory.[11] Our choice of cutoff informs the prevalence of positive serology, 36%, seen in this study. The use of a greater dilution to define positive serologic results would likely lead to a lower calculated prevalence, a lower positive predictive value, and a higher negative predictive value. In addition, the generalizibility of our findings may be limited in that women in the FACT study were all attempting to conceive.

In conclusion, self-reported history of CT infection has limited validity. Our findings have both clinical and public health implications. Many healthcare providers rely on patient reported history of previous CT infection to assess previous infection status. Our results suggest that self-report may not be reliable. In clinical assessments requiring high validity, such as in fertility assessments, serology should be considered. Our results also suggest a need for improved patient education. Patients should be provided information regarding the testing they are receiving, informed of the results of those tests, and understand the test results and their implications.

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Table 1.

Baseline demographic and behavioral characteristics of study participants by self-reported CT history & serologic status

	Positive Self-Reported CT History (n=108)	Negative Self-Reported CT History (n=301)	P value	Positive Serology (n=146)	Negative Serology (n=263)	P value
Age (y)*	26.3 ±4.6	28.4 ±3.8	<0.001	26.7 ± 4.4	28.5 ± 3.8	<0.0001
Race			<0.001			<0.0001
Black	78 (73.6)	90 (30.2)		104 (71.7)	64 (24.7)	
White	20(18.9)	186 (62.4)		30(20.7)	176 (68.0)	
Other/Multi racial	8 (7.6)	22(7.6)		11(7.6)	19 (7.3)	
Hispanic ethnicity	9(8.3)	24 (7.9)	0.9132	7 (4.8)	26 (9.9)	0.0685
Marital Status			<0.001			<0.0001
Single/Divorced/Widowed	40(37.0)	37(12.3)		49(33.6)	28(10.7)	
Living with partner	38 (35.2)	60 (20.0)		52(35.6)	46(17.6)	
Married	30(27.8)	203 (67.7)		45(30.8)	188 (71.8)	
Education			<0.001			<0.0001
HS diploma, GED, or less	41(38.0)	47(15.7)		49(33.6)	39 (14.9)	
Some college	52 (48.2)	79(26.3)		70 (48.0)	61(23.3)	
College or graduate degree	15(13.9)	174 (58.0)		27(18.5)	162 (61.8)	
Low SES†	68 (63.0)	87(29.2)	<0.001	94 (64.4)	61(23.5)	<0.0001
Birth Control Method			<0.001*			<0.0001*
Non LARC	20(18.6)	95(32.4)		25(17.2)	90(35.3)	
IUD	48(44.9)	153 (52.2)		76 (52.4)	125 (49.0)	
Implant	35 (32.7)	40(13.6)		38(26.2)	37(14.5)	
DMPA	4(3.7)	5(1.7)		6(4.1)	3(1.2)	
Insurance			<0.001			<0.0001
Private	35 (32.7)	213 (71.0)		51(35.2)	197 (75.2)	
Public	28(26.2)	32 (10.7)		36(24.8)	24 (9.2)	
None	44(41.1)	55(18.3)		58 (40.0)	41 (15.6)	
General Health‡			<0.001			<0.0001
Excellent to very good	48(44.4)	216 (71.8)		72 (49.3)	192 (73.0)	

	Positive Self-Reported CT History (n=108)	Negative Self-Reported CT History (n=301)	P value	Positive Serology (n=146)	Negative Serology (n=263)	P value
Good	42(38.9)	77(25.6)		56(38.4)	63 (24.0)	
Fair to poor	18(16.7)	8(2.7)		18(12.3)	8 (3.0)	
Current smoker	20(43.5)	34(32.7)	0.2044	28(45.2)	26(29.60)	0.0498
Current drug use	22(19.4)	36(12.2)	0.0316	32(21.9)	26 (9.9)	0.0008
Gravidity			<0.001			<0.0001
0	21(19.4)	128 (42.7)		26(17.8)	123 (47.0)	
1–2	57 (52.8)	115(38.3)		74 (50.7)	98(37.4)	
>3	30(27.8)	57(19.0)		46(31.5)	41 (15.7)	
Age at first pregnancy[§]	18.8±13.8	20.7±14.9	0.0012	18.7 ±3.7	21.2± 4.9	<0.0001

[*] Data shown as mean and standard deviation.

[†] Defined as receipt of public assistance or report of difficulty paying for basic necessities.

[≠] Assessed with the following question: "in general would you say your health is excellent, very good, fair, or poor?"

[§] Fisher's exact test

Table 2.

Serologic status by self-reported history of CT infection

	Positive Serology (n=146)	Negative Serology (n=263)
Positive Self-Report (n=108)	76	32
Negative Self-Report (n=301)	70	231

Sensitivity = 52.1% (95% CI, 43.6%, 60.4%)

Specificity = 87.8% (95% CI, 83.3%, 91.5%)

Positive Predictive Value = 70.4% (95% CI, 60.8%, 78.8%)

Negative Predictive Value = 76.7% (95% CI, 71.6%, 81.4%)

Table 3.

Adjusted odds ratios of baseline variables and self-reported history of CT infection and serologic results from multivariable logistic regression model.

	Self-Reported CT History OR 195% Cl)	Serology CT History OR (95% Cl)
Age (y)	0.89 (0.83, 0.93)	0.89 (0.85, 0.94)
Race		
White	Ref	Ref
Black	8.06 (4.64, 14.00)	9.53 (5.80,15.67)
Other/Multl-raaal	3.38(1.33, 8.58)	3.40 (1.47, 7.85)
Hispanic ethnicity		
No	Ref	Ref
Yes	1.05 (0.47, 2.33)	0.56 (0.19,1.08)
Marital Status		
Married	Ref	Ref
Living with partner	7.32 (4.06,13.18)	7.31 (4.15,12.89)
Single/Divorced/Widowed	4.29 (2.45, 7.49)	4.72 (2.83, 7.89)
Education		
HS diploma, GED, or less	Ref	Ref
Some college	0.76 (0.44,1.30)	0.91 (0.53,1.57)
College or graduate degree	0.10 (0.05, 0.19)	0.13 (0.07,0.24)
Low SES *		
No	Ref	Ref
Yes	4.12 (2.59, 6.55)	5.90 (3.78,9.19)
Most Recent Birth Control Method		
Non-LARC	Ref	Ref
IUD	1.31 (0.75, 2.27)	1.82 (1.11, 3.00)
Implant	3.65 (1.93, 6.89)	3.08 (1.68,5.66)
Insurance		
Private	Ref	Ref
Public	5.33 (2.86, 9.90)	5.79 (3.18,10.57)
None	4.87(2.86, 8.30)	5.46(3.30,9.05)
General Health †		
Excellent to very good	Ref	Ref
Good	2.46(1.51, 4.00)	2.37 (1.51, 3.72)
Fair to poor	10.12 (4.16, 24.64)	6.00(2.50, 14.40)
Current smoker		
No	Ref	Ref
Yes	1.58(0.78,3.23)	1.96(1.00, 3.87)
Current drug use		
No	Ref	Ref
Yes	1.88(1.05, 3.38)	2.56(1.46, 4.50)

	Self-Reported CT History OR 195% Cl)	Serology CT History OR (95% Cl)
Gravidity		
0	Ref	Ref
1–2	3.02(1.73,5.29)	3.57 (2.12, 6.01)
>3	3.21 (1.69, 6.08)	5.31(2.92,9.64)
Age at first pregnancy	0.91(0.85, 0.97)	0.87 (0.82, 0.93)

*Defined as receipt of public assistance or report of difficulty paying for basic necessities.

†Assessed with the following question: “in general would you say your health is excellent, very good, fair, or poor?”