Chlamydia trachomatis Genital Infections in a Community-based Family Practice Clinic

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Primary care physicians must become aware of the epidemiology and current diagnostic and management approaches to genital infections caused by Chlamydia trachomatis, since they are the most common sexually transmitted diseases in the United States. Clinical information was obtained on 282 sexually active female and 54 male patients aged between 14 and 44 years presenting for either asymptomatic physical examination or urogenital symptoms at a community-based family practice clinic that primarily serves middle socioeconomic class patients. A direct fluorescein-conjugated monoclonal antibody staining test for C trachomatis was found to be positive in 34 (12 percent) of 282 women and 15 (28 percent) of 54 men. Two (11 percent) of 19 pregnant women were found to be infected. Significantly more women presenting with urogenital symptoms or as a sexual contact of a symptomatic partner or those with abnormal findings on physical examination were found to have a positive test than were those who had no symptoms and no abnormal findings on physical examination. Similar trends were found in men, but were not statistically significant. It is recommended that primary care physicians presumptively treat those patients who have urogenital symptoms or have been exposed to sexual partners with urogenital symptoms and test asymptomatic patients who have signs of a possible C trachomatis infection.

C hlamydia trachomatis is now the most common of all sexually transmitted diseases. At least 3 to 5 million new cases are estimated each year in the United States, costing Americans more than $1 billion in health care dollars annually.[1,2] Complications of C trachomatis infections include cervical dysplasia, salpingitis, ectopic pregnancies, infertility, and neonatal transmission in women, and epididymitis and infertility in men.[1-4] C trachomatis may be the most common cause of infertility as a result of fallopian tube obstruction from acute salpingitis.[3,5] C trachomatis may also be the most common perinatal infectious agent.[6] The organism is responsible for approximately one half of all cases of nongonococcal urethritis,[7] the most commonly diagnosed sexually transmitted disease syndrome,[8] with an incidence that is increasing rapidly.[2] Some studies have reported at least 70 percent of female and up to 30 percent of male patients to have asymptomatic C trachomatis genital infections.[3,9,10] The prevalence of chlamydial infections ranges from 2 percent in some populations of asymptomatic pregnant women[3] up to 70 percent in those with acute salpingitis[11] or who are sexual contacts of men with nongonococcal urethritis.[8] Not unexpectedly, sexually transmitted disease clinics have the highest population prevalence, averaging approximately 30 percent.[3] Insufficient data are available concerning the epidemiology and approach to C trachomatis genital infections in primary care patient populations.[3]

Several demographic, historical, and physical factors have been shown to be associated with the isolation of C trachomatis in some populations.[3,12] Other studies, however, did not find these factors to be significant.[10,13-15] A direct specimen-staining technique with fluorescein-conjugated monoclonal antibodies to C trachomatis has been developed to test for the presence of this organism.[16-18] Therapy can prevent complications, resolve symptoms, and limit C trachomatis transmission.[19] No prior studies have used the fluorescein-conjugated monoclonal antibody test as a test of cure.

This study was designed to establish the prevalence of C trachomatis genital infections in a family practice clinic. The presence of infection in asymptomatic patients was prospectively compared with the presence of infection in

those who were symptomatic or had signs of possible C trachomatis infections over a 3.5-month period. Therapy protocols recommended by the Centers for Disease Control were used to treat patients with positive test results.

METHODS

The study population consisted of all consenting, sexually active male and female patients aged between 14 and 44 years consecutively presenting at a family practice clinic for routine annual physical examination or evaluation of urogenital symptoms. The study period extended from July 14, 1986, to October 31, 1986. Three hundred thirty-six of 349 patients agreed to participate in the study. Four men and two women who refused to give consent, five patients who had undergone total hysterectomies, and two patients who had not been informed of the study were excluded from the study. The family practice clinic is a community-based, medical-school-affiliated, accredited residency-training program. It serves approximately 11,000 middle socioeconomic class (income average approximately $32,500 per year) private patients from the metropolitan Kansas City area. More than 96 percent of payment to the clinic is in the form of fee-for-service or prepaid health plans, with less than 4 percent on Medicaid.

The reason for visit (chief complaint), age, sex, race, and marital status for each patient were obtained by a registered nurse. Next, each patient was seen by one of 23 physicians (18 resident and five staff physicians), who administered a standardized interview and physical examination according to instructed protocol.

The results of the examination for women were considered abnormal if abdominal tenderness, mucopurulent vaginal or cervical discharge, cervical erythema or friability, cervical motion or uterine tenderness, or adnexal mass or tenderness was found. Negative findings on examination excluded these physical findings.

The results of the examination for men were considered abnormal if penile discharge or epididymal or prostate tenderness was found. Negative findings on examination excluded these physical signs.

Female endocervical or male urethral specimens were then obtained, placed on single-well glass slides, fixed, transported, and processed with fluorescein-conjugated monoclonal antibodies to C trachomatis as previously described by Syva Company (Palo Alto, California).[20] Processing was performed by a federally approved Department of Health and Human Services pathology laboratory (Ost, Talbott, Smith, Galblum, Kansas City, Missouri). If five or more fluorescent elementary bodies were found, the fluorescein-conjugated monoclonal antibody test was considered positive.[20,21] The patient's usual charge for this test was $25 compared with $34 for cell culture.

TABLE 1. TREATMENT OF CHLAMYDIA TRACHOMATIS GENITAL INFECTIONS

Patient Condition	Recommended Therapeutic Protocol
Asymptomatic or uncomplicated endocervical or urethral infections	Doxycycline, 100 mg by mouth twice daily for 7 days
Acute salpingitis	Cefoxitin, 2 g intramuscularly, with probenecid, 1 g by mouth once, plus doxycycline, 100 mg by mouth twice daily for 10 days (unless hospitalization is required)
Epididymitis	Amoxicillin, 3 g by mouth, with probenecid, 1 g by mouth once, plus doxycycline, 100 mg by mouth twice daily for 10 days
Pregnant patients or doxycycline intolerance	Erythromycin ethylsuccinate, 800 mg, or erythromycin base, 500 mg, by mouth 4 times daily for 7 days
Doxycycline or erythromycin intolerance	Trimethoprim (160 mg)-sulfamethoxazole (800 mg) by mouth twice daily for 10 days

All patients who were found to have a positive fluorescein-conjugated monoclonal antibody test were treated. The treatment guidelines used in this study were those recommended by the Centers for Disease Control as outlined in Table 1.[3,22] Doxycycline was used rather than tetracycline for improved compliance.[2,22] Patients were advised to inform all partners with whom they had been sexually active during the prior month of their need to be evaluated and treated. Patients were advised to avoid sexual activity until reevaluated and found to have a negative fluorescein-conjugated monoclonal antibody test following therapy. Compliance with a prescribed therapy regimen was attested by each patient upon a scheduled two-week return visit to the clinic for reevaluation.

Chi-square analysis was used as appropriate for statistical analysis of the data collected. Bonferroni tables were used to verify statistical significance, since repeated chi-square statistical analysis using the same group of patients can distort the P value.[23]

RESULTS

The study population consisted of a total of 336 patients; 282 (84 percent) were women and 54 (16 percent) were men. A positive fluorescein-conjugated monoclonal an-

TABLE 2. CHARACTERISTICS OF FEMALE PATIENTS WITH CHLAMYDIA TRACHOMATIS INFECTIONS DIAGNOSED BY DIRECT FLUORESCEIN-CONJUGATED MONOCLONAL ANTIBODY STAINING TEST

Patient Characteristics	Number Positive/Total (%)*
Age (years)	
30 or less	29/187 (16)
Greater than 30	5/95 (5)
Race	
White	19/177 (11)
Nonwhite	15/105 (14)
Marital status	
Single (never married)	21/120 (18)
Married, divorced, separated	13/162 (8)
Reason for visit (chief complaint)	
Urogenital symptoms or pelvic pain	16/87 (18)
Partner with urogenital symptoms	2/4 (50)
Asymptomatic**	16/191 (8)
Physical examination	
Abnormal findings on examination***	22/123 (18)
Negative findings on examination	12/159 (8)
Total	34/282 (12)

Excluding those returning for reexamination and retesting
** Including those women presenting for annual examination, initial obstetric examination, or returning because of Papanicolaou smear dysplasia
*** Includes at least one abnormal sign (abdominal tenderness, mucopurulent vaginal or cervical discharge, cervical erythema or friability, cervical motion or uterine tenderness, adnexal mass or tenderness)

TABLE 3. CHARACTERISTICS OF MALE PATIENTS WITH CHLAMYDIA TRACHOMATIS INFECTIONS DIAGNOSED BY DIRECT FLUORESCEIN-CONJUGATED MONOCLONAL ANTIBODY STAINING TEST

Patient Characteristics	Number Positive/Total (%)*
Age (years)	
30 or less	13/31 (42)
Greater than 30	2/23 (9)
Race	
White	4/28 (14)
Nonwhite	11/26 (42)
Marital status	
Single (never married)	11/26 (42)
Married, divorced, separated	4/28 (14)
Reason for visit (chief complaint)	
Urogenital symptoms	9/31 (29)
Partner with urogenital symptoms	4/14 (29)
Asymptomatic**	2/9 (22)
Physical examination	
Abnormal findings on examination***	8/24 (33)
Negative findings on examination	7/30 (23)
Total	15/54 (28)

Excluding those returning for reexamination and test of cure
** Including those men presenting for annual examination
*** Includes at least one abnormal sign (penile discharge or epididymal or prostate tenderness)

tibody test for C trachomatis was found in 34 (12 percent) of 282 women and 15 (28 percent) of 54 men.

The demographic and clinical characteristics are summarized in Tables 2 and 3. The younger, nonwhite, and never-married patient categories had higher infection rates than the categories of those patients who were more than 30 years old, white, and had been married.

The mean age for women infected with C trachomatis was 24.8 (±3.3) years compared with 28.3 (±1.1) years for women who had a negative test. Eighteen (20 percent) of 91 women whose chief complaints were urogenital symptoms or who had sexual contact with a symptomatic partner had a C trachomatis infection. Comparatively, 16 (8 percent) of 191 women presenting for asymptomatic examinations (including annual and initial obstetrical examinations, and follow-up for dysplasia found on Papanicolaou smear) had an infection (P < .05). These 191 women presenting for asymptomatic examinations represented 68 percent of the 282 total women. Two (11 percent) of 19 women presenting for an initial obstetrical examination were infected with C trachomatis. Twenty-two (18 percent) of 123 women with abnormal findings on examination had a significantly higher rate of infection

than those 12 (8 percent) of 159 women without such findings on examination (P < .05).

The mean age for infected men was 24.1 (±5.3) years compared with 30.0 (±3.0) years for men who had a negative test. Men whose chief complaints were urogenital symptoms or who had sexual contact with a symptomatic partner or who had abnormal findings on examination had a higher rate of infection than those who did not, but these comparisons were not statistically significant. Nine (17 percent) of the total 54 men presented for asymptomatic examinations, and this group is too small to lead to statistically relevant conclusions.

Thirty-eight (78 percent) of the 49 infected patients who were treated returned for reexamination and fluorescein-conjugated monoclonal antibody retesting following therapy. Persistent urogenital symptoms or abnormal findings on examination were found in 12 (40 percent) of 30 women and one (13 percent) of eight men who returned. All patients who were compliant with the therapy regimen, which included their partners, had a negative test following therapy. One woman whose partner was noncompliant in taking the prescribed therapy was found to have a positive test following therapy. Compliance with retreatment resolved the infection.

DISCUSSION

This study has shown an overall C trachomatis genital infection rate from a community-based family practice clinic to be 12 percent for women and 28 percent for men. The prevalence of infection in the female patients was similar to that found in obstetric, family planning, or acute care clinics.[3,7] The prevalence in male patients was similar to that reported from sexually transmitted disease clinics.[7] The findings regarding the higher infection rates of men or women aged 30 years or younger, non-white, and single agree with prior publications.[3]

As in this study, other studies have also shown that most infected patients had urogenital symptoms or exposure to a sexual partner with such complaints. Patients who have symptoms or a symptomatic partner should, therefore, be treated for presumptive chlamydial infection.[3]

Careful examination may elicit physical signs suggestive of chlamydial genital infections. In the population studied, those with abnormal findings on examination had a higher infection rate when compared with those patients who had negative findings on examination. Since there were several observers in this study, these results may be extrapolated to physicians in other settings if those physicians are educated about symptoms and signs associated with an infection.

Since the consequences of untreated chlamydial genital infections can be so devastating, those sexually active women with the following signs should be tested and treated for C trachomatis: unexplained abdominal tenderness, an abnormal vaginal discharge, mucopurulent cervicitis, acute salpingitis, or acute urethral syndrome.[2–4,24,25] In this study, tests for other sexually transmitted diseases were performed only on symptomatic patients; therefore, association with C trachomatis was not analyzed. Further study is required when multiple infections are present.

In sexually active men, physical signs such as urethritis (scant watery or mucoid penile discharge or at least five leukocytes per high-power field magnification), epididymitis, and prostatitis have been associated with C trachomatis infection[4,26–28]; therefore, these patients should be tested and treated.

All patients who were compliant with their prescribed therapy regimen, which included treatment of their sexual partners, had negative findings on fluorescein-conjugated monoclonal antibody testing after therapy. The fluorescein-conjugated monoclonal antibody test was not compared with cell culture in this study; however, other studies have shown it to be a useful alternative to cell culture when culture diagnosis is not available.[3,15] The fluorescein-conjugated monoclonal antibody test requires further and comparative study with cell culture before its use as a test of cure can be recommended.

Prevention of C trachomatis infections and their potential complications can save patients from significant morbidity. Patients and physicians should be educated about this subtle, but debilitating, sexually transmitted disease and its increased risk from increased number of sexual partners. Barrier contraceptive methods (condom, diaphragm, or sponge) may decrease the transmission of chlamydial infections.[3,12] Early treatment can prevent infectious complications for patients and their prospective sexual partners or offspring.[3,29] All sexual partners during the month prior to diagnosis should be examined and treated. Also, to decrease sexual transmission, sexual contact with partners should be avoided until all are cured.[2,3] If primary care physicians presumptively treat those patients who have urogenital symptoms or have been exposed to sexual partners with urogenital symptoms and test asymptomatic patients who have signs of a possible C trachomatis infection, many potential complications may be prevented.

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Commentary

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Chlamydia trachomatis causes the most common sexually transmitted disease in the United States today. Most cases occur in asymptomatic women.[1-3] If potential complications are to be avoided, early diagnosis and treatment are necessary. Studies on this entity have mainly been performed in sexually transmitted disease clinics and family planning clinics, where the prevalence of infection is high. Fewer data are available regarding Chlamydia trachomatis infection in community-based populations. To identify patients with this organism, we need more information about its presentation in primary care populations—the above article by Saxer adds to this needed database. Dr. Saxer addresses the prevalence of Chlamydia trachomatis infection in a middle-class, community-based population and clarifies the similarity of risk factors in this group compared with those seen at high-risk clinics. His data also confirm that in a family practice, as in high-risk clinics, most patients with Chlamydia trachomatis are asymptomatic.

Saxer studied 282 middle-income women who were primarily white, married at least once, less than 30 years old, and asymptomatic. Of these, 12 percent had a direct immunofluorescence test positive for Chlamydia trachomatis. Analysis of the data indicated an increased risk for Chlamydia trachomatis in patients with factors previously found to be associated with infection in high-risk groups: patients younger than 31 years, never-married status, with urogenital symptoms, abnormal abdominal or pelvic findings on examination, or with sexual exposure to a symptomatic partner. The number of sexual partners was not reported.

The male patients evaluated were similarly young and married at least once, but were primarily nonwhite and symptomatic. Chlamydia trachomatis was identified by direct immunofluorescence test in 28 percent of these patients. The presence of this organism was associated with age 30 years or less and never-married status. There appeared to be an increased risk in men with symptoms, with abnormal physical findings, or with exposure to a sexual partner with symptoms. That these findings were not statistically significant is perhaps secondary to the limited power of the study (low number of men and very low number of asymptomatic men).

From the numbers given in the article, one can calculate additional useful information. Among women, the positive predictive value of each of the risk factors found to be statistically significant was small—ranging from 11 to 18 percent. Also, the presence of Chlamydia trachomatis would have been missed in 35 to 50 percent of women if the presence of symptoms or abnormal physical findings

or never-married status had been used as screening criteria. The sensitivities of using combinations of these risk factors were not reported. Consequently, while these risk factors help identify a high-risk group for infection, they fail to address the problem of identifying the sizable number of remaining asymptomatic women who are at increased risk for complications of untreated disease.

Some consensus has been achieved regarding recommendations for testing and treating patients with known risk factors for Chlamydia trachomatis. These recommendations include treating patients with entities known to be highly associated with Chlamydia: pelvic inflammatory disease, mucopurulent cervicitis, nongonococcal urethritis, Neisseria gonorrhoeae, and epididymitis in men younger than 36 years, as well as patients with sexual partners having these diseases.[4] Some support testing these patients with cell culture or direct immunofluorescence tests followed by empirical treatment. This course would maximize accurate diagnosis, improve physician diagnostic acumen, and improve patient education and compliance with treatment.[5] All agree these patients should be evaluated or treated, and this article by Saxer supports these recommendations.

Unfortunately, these risk factors are not positive in the majority of patients with Chlamydia trachomatis. There is less consensus regarding the approach to these asymptomatic patients. Factors previously shown to be associated with an increased risk of chlamydial infection in some but not all studies include:[4]

1. Young age (<20 or 30 years of age)
2. Cervical friability
3. Nonwhite ethnic group
4. Use of nonbarrier contraception or oral contraceptives
5. Inflammatory changes on Papanicolaou smear
6. Increased number of sexual partners

Findings on these factors vary among studies, and clear-cut guidelines have failed to emerge.

How then do we decide whom among our asymptomatic patients to evaluate for this potentially morbid disease? The effectiveness of screening asymptomatic populations for Chlamydia trachomatis can be evaluated using criteria suggested by Frame and Carlson.[6] Disease caused by this organism meets the majority of the criteria for screening as follows:

1. *The disease has a significant effect on quality or quantity of life.* The association of Chlamydia trachomatis with serious genitourinary infections has been proven. Furthermore, this organism is associated with endometritis, infertility, neonatal conjunctivitis and pneumonia, prematurity, and low birth weight. Sexual transmission is common, magnifying the effect on the population.

2. *Acceptable methods of treatment are available.* Most often used are tetracyclines, erythromycin, or trimetho-

prim-sulfamethoxazole. Side effects are minimum, and efficacy is good.

3. *The disease has an asymptomatic period during which treatment is thought to reduce the risk of morbidity.* Controlled studies comparing long-term outcome in treated and untreated patients are lacking, and probably cannot ethically be performed. Untreated, asymptomatic Chlamydia trachomatis cervicitis is thought to progress to pelvic inflammatory disease in 20 to 30 percent of patients[7] and cost over $1.4 billion per year in direct and indirect costs—primarily owing to sequelae of untreated, uncomplicated infections.[8] Treatment prior to development of complications would be expected to lower these risks.

4. *The result of treating screened patients is superior to treating only after symptoms occur.* Attempted treatment for illness, infertility, prematurity, and neonatal disease is not always successful. Prevention of these syndromes would clearly be preferable.

5. *Tests are available at a reasonable cost to detect the condition in the asymptomatic period.* The best studied of these include direct immunofluorescence testing ($12 to $25) and cell culture ($20 to $40).

6. *The cost of the screening has been justified.* In populations with an estimated prevalence of Chlamydia trachomatis of greater than 14 percent, the use of routine cell culture for this organism has been shown to be cost effective.[9] In populations with prevalence of 7 to 8 percent or greater, use of the direct immunofluorescence test as a routine screen is advocated.[9,10] In communities with less risk, recommendations are unclear. Identification of similar risk factors from populations of varying prevalences of Chlamydia trachomatis indicates testing those patients with the risk factors described above (young age, new sexual partners, etc) may be one way to identify asymptomatic patients. Further study is needed on this low-risk population.

Special consideration should be made for patients who are pregnant. They are as likely to have Chlamydia trachomatis infection as are other patients.[2,11,12] The added risks to the mother, fetus, and newborn, however, make detection and treatment crucial. These risks include prematurity,[11,13] low birth weight,[12] stillbirth or neonatal death,[11,13] and endometritis[14] as well as neonatal pneumonia and conjunctivitis.[14] Some suggest screening all unmarried pregnant women and those with one or more risk factors.[15] Screening all pregnant adolescents has also been suggested.[2] Screening all prenatal women is cost effective in populations in which the prevalence of infection is greater than 6 percent.[16]

All clinical tests have limitations, and those used in testing for Chlamydia trachomatis are no exception. Direct immunofluorescence tests have been reported to have sensitivities varying from 61 to 100 percent, with positive predictive values compared with cell culture ranging from

65 to 93 percent. These discrepancies may be due to several factors, including limitations of the tests themselves; training, experience, and supervision of personnel; and differences in quality control.[17] Cell cultures, although diagnostic of infection when positive, are difficult to perform and depend on the presence of viable organisms; hence, they too are not 100 percent sensitive.[18] Low positive predictive values of the direct immunofluorescence test could therefore have been exaggerated by false-negative cell cultures. At this time, however, the cell culture is still considered the "gold standard." Because of the social and emotional implications of the diagnosis of a sexually transmitted disease, positive direct immunofluorescence tests may be followed with cell culture to rule out the majority of false-positive tests. If the patient and partner(s) are willing to accept treatment without this confirmation, treatment is suggested. In light of the above limitations, one must continue to be aware of the possibility of false-positive and false-negative tests and, if needed, treat the patient, not the test.

In summary, firm guidelines exist for treating, with or without testing, patients at high risk for chlamydial infection. Furthermore, it is cost effective to screen those patient populations with a disease prevalence of 12 percent or greater with cell culture, and 7 percent or greater with the direct immunofluorescence test. While no consensus exists regarding the screening of patient populations with a lower prevalence of infection, a prudent strategy at this time would be to screen all pregnant women, plus women with any of the risk factors described above. These recommendations can then be adjusted as further studies, such as the one by Saxer in this issue, continue to clarify the utility of screening primary care patients based on the presence of risk factors.

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