Letter to the Editor

Comparison of two molecular methods for diagnosis of *Chlamydia trachomatis*

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Key words: *Chlamydia trachomatis*; sexually transmitted diseases; BD ProbeTe ET System; one tube nested PCR

J Infect Dev Ctries 2013; 7(1):064-066.

(Received 19 June 2012 – Accepted 25 October 2012)

Introduction

Chlamydia trachomatis is an obligate intracellular microorganism responsible for several diseases. It is considered the most common bacterial sexually transmitted infection (STI) worldwide. The World Health Organization (WHO) estimates that 92 million new cases of *C. trachomatis* occur globally every year. An estimated 3 to 4 million new cases are diagnosed every year in the United States, 5 million in Western Europe, and 16 million in sub-Saharan Africa [1]. According to estimates from the Centers for Disease Control and Prevention (CDC), 75% of new cases in the United States are diagnosed in asymptomatic women. The sequelae of chlamydial infection in women are severe and can lead to serious complications, including pelvic inflammatory disease, ectopic pregnancy, infertility, and chronic pelvic pain [2,3]. Chlamydial genital infections have also been reported to increase human immunodeficiency virus transmission and influence the development of human papillomavirus-induced adenocarcinoma [4,5,6]. In addition, pregnant women infected with *C. trachomatis* put their children at risk for conjunctivitis and pneumonitis through mother-to-child transmission [7]. In men *C. trachomatis* is associated with non-gonococcal urethritis and epididymitis [8]. In the male high-risk group, 50% are asymptomatic with mild symptoms.

Today, sexually transmitted diseases are major and ever-expanding public health and social problems because of an increased rate of *C. trachomatis* infection in both the female and male population within the sexually active 20- to 30-year-old group [9,10,11]. Several hypotheses may explain the rise of chlamydial infections, including changes in sexual behavior and insufficient knowledge of sexual life and sexual health. Moreover, the use of more sensitive tests may contribute to the rising rates. In Northern Sardinia as well, the problem is rising among young people [12]. For this reason, screening programs must be implemented to prevent morbidity. Furthermore, a rapid diagnosis of the microorganism is essential to reduce the transmission of infection, most of all in young people.

The study

The objective of this study was to compare two methods for the detection of *C. trachomatis*: the BD ProbeTec ET System (Becton Dickinson, Franklin Lakes, United States), performed according to the manufacturer's instructions, versus an in-house one tube nested PCR performed as previously published [13]. The BD ProbeTec ET System is the first real-time DNA amplification assay for the detection of *C. trachomatis*; it is a rapid test that can be used to screen extragenital as well genital specimens.

In this study we evaluated a total of 511 samples collected in one year from both male (aged 20 to 65 years) and female (aged 15 to 35 years) patients with suspected sexually transmitted infections as follows: 330 cervical swabs, 34 vaginal swabs, 94 semen samples, 35 urine samples, 7 urethral swabs, 6 conjuntival swabs and 5 samples from other body

areas. According to Italian law informed consent was not necessary.

C. trachomatis *detection in female samples*

Of the 330 cervical swab specimens tested, 11 (3.3%) were positive by the BD ProbeTec ET System, while 10 (3%) were positive by the nested PCR. Of the 34 vaginal swabs only one was positive by the BD ProbeTec ET System, but no sample was positive by the nested PCR. Of the 16 urine samples, 5 were positive by the BD ProbeTec ET System, and only two were positive by the nested PCR. One sample of pus was positive by both methods.

C. trachomatis *detection in male samples*

A total of 126 samples were tested. Of the 94 semen samples tested, only one was positive by the BD ProbeTec ET System but negative by the nested PCR. Eleven samples were indeterminate using the BD ProbeTec ET System; these were repeated and resulted negative. The other male samples were all negative.

Regarding the prevalence of *C. trachomatis* in non-pregnant women, Adams [14] published a review study in which the prevalence was stratified by age. The highest prevalence was observed in the under 20-year-old age group with 8.1%, declining up to 1.4% in those aged over 30 years.

In our study, we found 12 positive samples in endocervical swabs out of 280 from women aged between 20 to 30 years and 5 positive out of 13 in urine samples. Furthermore, we analyzed 23 endocervical swabs from pregnant patients. We obtained 14 (61%) positive samples using the BD ProbeTec ET System and 13 (56%) positive samples by nested PCR. Other samples from a group of 20- to 35-year-old patients were negative.

The sensitivity, specificity, positive and negative predictive values (PPV and NPV) were 95%, 100%, 100% and 99% for the BD ProbeTec ET System and 65%, 100%, 100%, and 98% respectively, for the nested PCR method.

We observed a good agreement between the two systems for detection of *C. trachomatis*. Concordance was high (0.988) between the two assays, and the degree of agreement kappa (k = 0.807) was very good.

Conclusions

An infection with *C. trachomatis* is characterized as a colonization of the cervix or urethra, independent of clinical symptoms [15]. The estimated prevalence of infected sexually active women varies worldwide from 2.2% to above 20% in high-risk populations, with different percentages based on age and ethnicity within the same country [16]. The reported prevalence varies widely, but most commonly reported infection rates ranged between 4% and 6% among European non-pregnant women [17].

Our study involved a large and representative group of young women; the age shift prevalence among young women observed in our study has also been highlighted by research groups worldwide in various populations. This concordance confirms the importance of screening for chlamydial infections to control asymptomatic/latent sexually transmitted diseases and to correctly diagnose the disease, which may have overlapping signs and symptoms patterns with other diseases. Women aged under 25 years should be the target of a *C. trachomatis* screening program, as in other screening programs worldwide [18].

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Conflict of interests: No conflict of interests is declared.