MEDICAL CHANNEL

Original Article

DETECTION OF CHLAMYDIA INFECTION AMONG WOMEN: A COST EFFECTIVE STUDY IN PUBLIC SECTOR TERTIARY CARE HOSPITAL

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ABSTRACT:

Objective: To evaluate the incidence of Chlamydia infection in female population by considering cost effectiveness of tests.
Place & Duration of Study: This study was conducted at Civil Hospital Karachi, Pakistan from May 2008 to June 2009.
Methodology: Incidence of Chlamydia infection among women was determined through endocervical specimens collected from all women. The first specimen taken was transferred on slides to perform direct fluorescent antibody test (DFA) and second specimen was used for Becton Dickinson Probe Tec ET system (BDPT). Those specimens which were detected to have C.trachomatis DNA with the BDPT were accepted as positive. The data was expressed in terms of mean and percentages with a confidence interval of 95%. Analysis was done on SPSS version 16.0.
Result: Out of 230 patients selected for the study, 138 cases were of symptomatic where as 92 cases were asymptomatic. C. trachomatis was detected in 20 out of 138 (14.49%) cases of symptomatic and 11 out of 92 (11.9%) cases of asymptomatic with DFA and BDPT techniques. The sensitivity and specificity of DFA were 67.2% and 94.0% respectively. While they were 75% and 95% for BDPT.
Conclusion: Both DFA & DBPT tests are easy to perform and cost effective for developing countries.

Key Words: C.trachomatis, Sexually transmitted diseases, Symptomatic disease, asymptomatic disease.

INTRODUCTION

Genital infection due to Chlamydia trachomatis (CT) is one of the most common sexually transmitted disease (STD) worldwide. It represents an estimated 92 million new cases of CT infection that occur each year. More than two-third of these cases occur in the developing world, where diagnosis and treatment services are almost absent[1].
CT infections are often asymptomatic and can cause pelvic inflammatory disease (PID), cervicitis, salpingitis, urethritis, and postpartum endometrititis[2].
Traditional laboratory diagnosis of these infections is done by antigen detection for CT. This antigen detection has been done by using Elisa technique and direct fluorescent Assay (DFA). In developing countries, this principal detection method of CT infection is still a method of choice. Further, Becton Dickinson Probe Tec ET system (BDPT), that uses strand displacement amplification to detect CT infection, is also used. However, this technology is similar to PCR but it uses restriction enzymes instead of synthetic oligopeptides[4].
Recently, nucleic acid amplification tests (NAATs) have become widely used; these tests

have shown a greater sensitivity and have improved the ability to detect CT infection[3].NAATs are critical new tools to diagnose CT. Commercially available NAATs using methods such as PCR, ligase chain reaction (LCR) strand displacement amplification and transcription-mediated amplification (TMA) are now the 'gold standard' tests for genital Chlamydia infection and are increasingly used in screening for STD infection in developed countries. However, this technique is not available in every tertiary hospital and it is alsonot cost effective and thus not affordable to common people.

Further, despite the high prevalence of sexually transmitted infections in developing countries, the laboratory confirmation of infection is not carried out because of poor resource settings and due to lack of simple, cost effective diagnostic tools. This prompted WHO to emphasize on approach, based on syndromes, for case management in developing countries, in which either a significant proportion of genital Chlamydia are miss out or false positive test leading to treatment even in the absence of infection.

Therefore, the aim of the present study is to investigate the efficacy of DFA test and its comparison with BDPT in the detection of CT incidence by keeping cost effectiveness in mind.

MATERIALS AND METHODS

Enrollment of patients

Total 230 married woman out of 1500 (median age 28 years and range between 15-55 years), visiting gynecological department were enrolled for the study between May 2008 to June 2009.

After taking the approval of Ethics Committee and adoption of appropriate research tools,all of the participants were informed of the purpose and procedure of research and their consent was also taken. Demographic data and other information were routinely collected from all the women, using standardized data collection.

These participants were divided into two groups:

i) Symptomatic; who had various symptoms such as vaginal discharge, pelvic pain, dysuria (n=138).
ii) Asymptomatic; those women who applied to the hospital for a routine checkup (n=92).

Exclusion Criteria:

The patients who received antibiotic therapy within two weeks of sampling, who had some definite diagnosis etiology and predisposing factors for their complaints were excluded.

Experimental Protocol:

A thorough vulval examination was done for lesions and vaginal/cervical discharge. Per speculum examination was carried out. After cleaning the exocervix with cotton swab to remove mucus and exudates, the first specimen collected was smeared on a clean glass slide, air-dried for DFA test. Slides were processed and stained according to the instructions given in the kit's manual. Slides were screened with a fluorescent microscope at 400X magnification and confirmed at 1000X. The tests were considered positive if 10 or more elemental bodies were identified. DFA specimens were considered inadequate if less than 10 endocervical cells were present on a smear.

The collection of second specimen was according to BDPT technique and its weight transport system. These collected specimens were then transported to the laboratory for culture.

Sensitivity, specificity, Positive predictive values were calculated with 95% confidence intervals to test the significance for the statistical analysis of the collected data using SPSS.

RESULTS

According to the results presented in Table 1, the Symptomatic group includedabdominal pain in 54.34%, followed by fever in 18.11% and vaginal discharge in 14.49%, of the enrolled symptomatic patients.

In this study, DFA and BDPT test results for the detection of CT were evaluated on the basis of detection of CT-DNA with BDPT technique and thus accepted as positive. Accordingly as shown in Table II, CTwas detected in 20 specimens of symptomatic group (14.49%) and 11 in asymptomatic group (11.9%). No statistical difference was detected between these two groups in terms of the rates of detection of CT (p=0.177).

Out of 230 cases, 23 samples were considered true positive as both DFA and BDPT were positive while remaining 188 samples were considered true negative as they test negative both by DFA

TABLE-I

DISTRIBUTION OF VARIOUS SYMPTOMS DETECTED IN WOMEN IN SYMPTOMATIC GROUP.

Symptoms	Symptomatic group Total (n=138)
Abdominal pain	75 (54.34%)
Fever	25 (18.11%)
Anexal sensitivity	12 (8.69%)
Abnormal cervical or vaginal discharge	20 (14.49%)
Infertility	6 (4.34%)

TABLE-II

COMPARISON BETWEEN CT INFECTION FOUND IN SYMPTOMATIC AND ASYMPTOMATIC PATIENTS

CT Infection	Symptomatic	Asymptomatic	P*
Abnormal cervical or vaginal discharge	20 (14.49%)	11 (11. 9%)	P=0.177

TABLE-III

CROSS COMPARISON OF DFA AND BDPT TESTS FOR THEINVESTIGATIONOF C. TRACHOMATIS IN ENDO-CERVICAL SPECIMENS OF PATIENTS

CT TESTS			BDPT	
			n (%)	
			Positive	Negative
DFA	n (%)	**Positive**	23 (10%)	11 (5%)
		Negative	08 (4%)	188 (82%)*
		Grand Total	**230**	

*Both tests are negative

TABLE-IV

COMPARISON OF SENSITIVITY, SPECIFICITY&POSITIVE PREDICTIVE VALUEFOR DFA TEST WITH BDPT IN THE DIAGNOSIS OF C. TRACHOMATIS

Specimens	Test	Sensitivity		Specificity		Positive Predictive Value	
		(%)	95% CI	(%)	95% CI	(%)	95% CI
(n=230)	DFA	67.6	39.0-93.9	94	95.6-99.1	53.33	26.5-78.7
(n=230)	BDPT	75	28.3-99.4	95		100	98.4-99.9

and BDPT assay (Table III).

Over all incidences of CT infection was10% (Table III), including reproductive age of the participants (70% of the total). The reproductive age was ranging between 18 to 40 years (data not shown).

A comparison of DFA and DBPT tests with respect to their sensitivity and specificity has been presented in Table IV.

DISCUSSION:

The incidence of Chlamydia trachomatis is comparable to the prevalence in developing countries. In our study overall prevalence of CT as detected by DFA and BDPT was 13.4% and the difference between two groups (symptomatic and asymptomatic) was not significant. Comparing it with international data, CT infection found to be 16.2% among patients attending STD clinic at new Delhi[5.]In another study done in the women who applied to the family planning clinic in Trabzon, Turkey, the frequency of CT was found to be 12%[6]. High chlamydial infection has also been reported in Manila 23.3% Cebu. Philippines 37.0% and 14.0% in Nicaragua[7, 8.]

There are few studies comparing the prevalence of CT in symptomatic and asymptomatic as in the present study. In one of these studies, endocervical smear specimens of 16,834 women investigated by PCR method and PCR positive results were obtained in 4.1% of 80,000 symptomatic women and in 2.9% of 8,834 asymptomatic women[9].Study done in Italy, the serological markers of women was examined and they found a significant difference in symptomatic and asymptomatic women regarding the presence of CT (3.4 versus 20%) [10.]However, in the present study, there was no statistically significant difference in the two groups (Table II).

Among the specimen evaluated in the present study, the sensitivity and specificity of DFA was found to be 67.6%, 94%, respectively as shown in Table IV. The estimated sensitivity and specificity of DFA is 61.0% to 92.2% and 99 to 100%, respectively (in different laboratory settings) when compared to other studies[11.]

NAAT based diagnostic kits that were shown to be highly sensitive 92.9%, 100% and specific (99.0 to 100%) for CT detection[12, 13], could not be adopted for routine diagnosis on the basis of the high cost involved. However, in the present study the sensitivity and specificity were found to be 75 and 95% respectively and therefore these routine tests can be used effectively in the diagnosis of CT infection where the facilities of NAAT are not available.

In our study CT infection were more prevalent in the reproductive age group being 70% as mentioned in the results.However, other studies reported high prevalence in sexually active individuals associated with younger age in black race [14].While, in a contrast study reported for Turkey,CT was more prevalent in more advance age (Mean age 33.69+3.5 years) [15.]

CONCLUSION:

Both DFA & DBPT tests are easy to perform and cost effective for developing countries. It is therefore suggested that instead of asking for NAAT, poor population can get benefit of women health care with respect to eradication of CT infections.

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