EVALUATION OF THE RAPID IMMUNOCHROMATOGRAPHIC TEST AGAINST GOLD STANDARD RT-PCR IN GENITAL C. TRACHOMATIS INFECTION IN SEXUALLY ACTIVE WOMEN.

Microbiology

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ABSTRACT

Chlamydia trachomatis is the leading cause of sexually transmitted infections (STIs) worldwide. Chlamydial infection if undiagnosed and untreated can result in Pelvic Inflammatory Disease (PID), ectopic pregnancy, and infertility. The present study aimed at detecting the prevalence of C. trachomatis in endocervical samples of symptomatic women attending gynecology OPD. 50 cases of sexually active women were included in the study and samples were tested by both rapid immune chromatographic test and RT-PCR. The rapid test was evaluated against RT-PCR in detection of C. trachomatis in endocervical samples. In this study the prevalence of C. trachomatis as detected by PCR was 14% Screening symptomatic women in reproductive age group along with syndromic management can able to reduce the burden of the disease in this community. The sensitivity of POC rapid test used in this study was found to be low. Hence it is necessary to improve the standards of POC rapid test which would be much useful for screening in developing countries like India.

KEYWORDS

chlamydia infection, sexually transmitted disease, endocervix, PCR.

1. INTRODUCTION

Sexually transmitted infections (STI) are a major global cause of acute illness with severe medical and psychological consequences[1]. Complications of STDs with severe sequelae may result in chronic pelvic pain, tubal pregnancy and the costliest complication of infertility[2]. Hence timely and precise diagnosis of these infections is mandatory. Chlamydial trachomatis is leading cause of sexually transmitted infections (STIs) worldwide. Chlamydial infection if undiagnosed and untreated can result in Pelvic Inflammatory Disease (PID), ectopic pregnancy, and infertility. Chlamydia is a risk factor in HIV infections by increasing in the transmission rate from 3 to 6 times and it also has a cofactor in the development of cervical carcinoma[345]. Symptomless patients are the reservoir for the C. trachomatis. During pregnancy, chlamydial infection may cause complications such as spontaneous abortion, premature rupture of fetal membranes, premature delivery, low birth weight and neonatal infections like conjunctivitis and pneumonia. Economic burden of testing and poor performance of the available tests are the major obstacles to Chlamydia screening programs in India. Instead of relying on microbiological testing, clinics in resource-poor settings continue to employ syndromic management for sexually transmitted infections, that lacks specificity for C. trachomatis infection[7]. Blind use of antibiotics for C. trachomatis also enables resistant strains to evolve rapidly. Therefore, a vital need is felt to actively diagnose the disease. The polymerase chain reaction technique has been used in the diagnosis of Chlamydia

2. AIM

- Find out the prevalence of genital C. trachomatis infection in sexually active women.
- To evaluate the rapid immunochromatographic test against gold standard RT-PCR.

3. MATERIALS AND METHOD

The present study was conducted at the Department of Microbiology, Tirunelveli Medical College, Tirunelveli. The study sample collection was done according to the manufacturer’s guidelines. All the laboratory works were carried out as per standard laboratory procedures and Bio-safety norms in class II biosafety cabinet. Before starting the purification reaction, water bath was set to 56°C and the elution buffer was warmed up to 56°C.

4. RESULTS

Table 1: Comparison of RICT With RT-PCR In Detection Of Chlamydia Trachomatis.

<table>
<thead>
<tr>
<th>Test</th>
<th>Samples tested</th>
<th>Positive Cases</th>
<th>Negative Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Positive %</td>
<td>Negative %</td>
</tr>
<tr>
<td>RT-PCR</td>
<td>50</td>
<td>7</td>
<td>43</td>
</tr>
<tr>
<td>ICT</td>
<td>1</td>
<td>2</td>
<td>49</td>
</tr>
</tbody>
</table>

The above table shows all the 50 samples were tested with RT-PCR and ICT for C. trachomatis from genital samples. Out of this 14% were positive by RT-PCR and 2% by ICT.

Table 2: Evaluation Of Rapid ICT Against RT-PCR

<table>
<thead>
<tr>
<th>ICT</th>
<th>RT-PCR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>positive</td>
</tr>
<tr>
<td>positive</td>
<td></td>
</tr>
<tr>
<td>negative</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>7</td>
</tr>
</tbody>
</table>

Table 3: Age Wise Distribution Of Chlamydia Trachomatis Positive Cases

<table>
<thead>
<tr>
<th>AGE (years)</th>
<th>Positive cases</th>
<th>Negative cases</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>%</td>
<td>No</td>
<td>%</td>
</tr>
</tbody>
</table>

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5. DISCUSSION

C. trachomatis is the most common cause of sexually transmitted disease in women of reproductive age group. The major causes of concern are due to sequelae like pelvic inflammatory disease and infertility. In developing countries like India, syndromic management is in progress to treat the sexually transmitted disease. Various studies imply that syndromic approach in treating genital discharge syndrome has poor performance. So in countries like India with low return rates of patients, efforts are made to improve diagnostic tools on the basis of WHO (ASSURED) criteria for POC tests. In this background this study attempts to evaluate a rapid immunochromatographic test with the gold standard RT-PCR. Sexually active females are prone for C. trachomatis and the major morbidity is infertility so the population taken for this study included patients between 20 to 40 years. This was similar to the prevalence study done in Chennai by Prabhu N et al. This is because younger age group is often related to difference in sexual behavior. Vaginal discharge was the major clinical symptoms in the study group followed by dysuria, lower abdominal pain and dyspareunia. Macropurulent cervicitis was the predominant sign followed by cervical ectopy and erosion. The prevalence of Chlamydia trachomatis was 14% by RT-PCR in this study. This is comparable to the study by Pandya et al, in Gujarat where the prevalence was found to be 12%. The study by Jayant et al, found Chlamydial prevalence to be 20% among lower genital infections. The study by Jay et al. found the prevalence of genital Chlamydia in 11.3% [3]. However a study conducted in high risk population by Sood et al., found the prevalence of Chlamydia trachomatis to be 20% among lower genital infections. The study by Jay et al. among normal population showed a prevalence of 1.1% This varied prevalence rates may be due to different diagnostic methods and different population. The introduction of a commercial nucleic acid amplification assay that can be integrated into routine clinical microbiological laboratory is an important advance in diagnosing chlamydial infections. Since PCR has improved performance over culture and antigen based tests with highest sensitivity and specificity, it makes the test as gold standard diagnosis for C.trachomatis. PCR detects even a single copy of DNA in a clinical sample. RT-PCR has an advantage of quantification of the chlamydial load in the specimen. It can be done by CT values which are inversely proportional to the chlamydial load. Though plasmid based primers are more sensitive we used major outer membrane protein (MOMP) as a target for primer because of emerging plasmid less strains. Horizontal and vertical PCR contamination with amplicons is an essential drawback of PCR especially when processing more numbers of samples. This contamination may be nullified by using closed systems such as the one that was used in this study. (Bio-Rad). In this study, the sensitivity of ICT was 14.2%, which is very low where as the specificity was 100% when evaluated against RT-PCR. This is similar with a study reported by Van Dommelen et al where the sensitivity of three rapid EIA's was extremely low (12% to 27%) compared to PCR. The study by Rani R et al. evaluated a rapid test and observed that it had a sensitivity of 25% and 100% specificity. The study done by Sabidó M et al, evaluated a rapid test and observed that it had a sensitivity of 25% and 100% specificity. However Lourdes Mahilum-Tapay et al. evaluated a rapid test and observed that it had high sensitivity and specificity, 83.5% and 98.9% respectively. In contrast Naviyot K. Vidwan et al. did a study from vellore and evaluated the FDA approved ICT[7]. He concluded that it had very poor performance in low prevalence community with 0% sensitivity and 90% specificity. In this study the prevalence of C. trachomatis was 14% among symptomatically active females. ICT has detected 2% of the positive cases. Ureda et al. stated that a test that requires no laboratory testing, is sensitive and specific to 99% and averts 16.5 million incidence of Chlamydia infections[8]. Vickramen et al. stated that point of care with moderate sensitivity could identify more infections than gold standard tests. POC tests support the use in scenarios where it would be difficult to ensure a high return rate, failure to trace the contact and where there is high potential for further STI transmission. However our results showed poor sensitivity of 14%. Thus it may be unaffordable by those at risk of infection; Sensitive-false negatives; Specific-few false positives; User-friendly-simple to perform; Rapid and Robust-to enable treatment at first visit (rapid) and does not require highly trained personnel to perform. However PCR is highly sensitive and specific, the high price of the commercial kits and lack of proper infrastructure are the major drawback for using them for large screening programs in developing countries like India. A POCT setting using a test that meets the criteria of “ASSURED” to afford an rapid diagnosis and to initiate prompt and proper treatment, seems to be best policy in facing chlamydial infections. Thus there is an urgent call for improved and cost effective diagnostic tests that will decrease the burden of C.trachomatis infections in the developing countries. The sensitivity of POC rapid test used in this study was found to be low. Hence it is necessary to improve the standards of POC rapid test which would be much useful for screening in developing countries like India. Further molecular studies are essential to know the accurate information of zero types which will be helpful in formulating vaccines in future for at least reproductive age group.

7. REFERENCES:

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