Clinical Background and Detection of *Chlamydia trachomatis* Antigen among Infertile Women Attending University of Maiduguri Teaching Hospital, Nigeria

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Authors' contributions

Article Information

Original Research Article

ABSTRACT

Background: *Chlamydia trachomatis* infection is an established cause of pelvic inflammatory disease (PID), ectopic pregnancy, chronic pelvic pain and infertility among women. It is the most common bacterial sexually transmitted disease in the world. The infection is largely asymptomatic.
Aim: The study was carried out to determine the Clinical background as well as detect the *Chlamydia trachomatis* antigen among infertile women attending University of Maiduguri Teaching Hospital (UMTH).

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Methods: A survey on the Clinical background and antigens to *Chlamydia trachomatis* was carried out among infertile and post natal women attending fertility Clinic UMTH. A total of 65 endocervical swab samples were collected from the aforementioned group of subjects within the age of 18-47 years, out of which 45 were collected from infertile women while the remaining 20 were obtained from post-natal women to serve as control subjects. The samples were analysed by using Chlamydia Rapid Test device swab/urine (Abon Biopharm(Hangzhou), Co., Ltd) that work on the principle of immunochromatographic technique.

Results: Highest number of infertility was observed on women within the age of 30-35 years (33.3%). The result shows that those that attained tertiary educational level have the highest number of infertility (60%). The study demonstrated highest number of infertility among female civil servants (53.3%) followed by full-time house wife (33.3%). More infertility was observed among women who are not engaged in the use of contraceptive measures (95.6%). The overall result from this study shows no prevalence (0.0%) of *C. trachomatis* genital infection among infertile women in UMTH.

Conclusion: Further research using more sensitive and specific procedures for the detection of *C. trachomatis* from clinical specimens such as nucleic acid amplification tests and cell culture are recommended among infertile women in Borno State, Nigeria.

1. INTRODUCTION

Infertility refers to an inability to conceive after having regular unprotected sex [1]. Infertility can also refer to the biological inability of an individual to contribute to conception or to a female who cannot carry a pregnancy to full term. In many countries infertility refers to a couple that has failed to conceive after 12 months of regular sexual intercourse without the use of contraception [1].

Chlamydia trachomatis is the most prevalent sexually transmitted bacterial infection worldwide, with an estimated 4-5 million new cases each year. *Chlamydia trachomatis* is the most implicated organism in infertility [2]. Up to 40% of women with untreated Chlamydia develop symptomatic Pelvic Inflammatory Diseases. Untreated cases of Pelvic Inflammatory Diseases due to Chlamydial infection may result to complications ranging from chronic pain, ectopic pregnancy and infertility [1]. In many developed countries, screening for *Chlamydia trachomatis* has been set up to reduce transmission and reproductive tract morbidity, however, in developing world, laboratory services for sexually transmitted infections (STIs) are either not available, or where limited services are available, patients may not be able to access those services [3]. Against this backdrop, this study was carried out to determine the Clinical background and to detect antigens to *C. trachomatis* among infertile women attending fertility clinic of UMTH, with the view to determine the predisposing factors and device ways forward.

2. MATERIALS AND METHODS

2.1 Study Area

The study was conducted in the University of Maiduguri Teaching Hospital (UMTH) which is a tertiary health centre located within Maiduguri north-eastern Nigeria. Maiduguri is located in the North-Eastern part of Nigeria. Its geographical coordinates are latitude 115°N and longitude 135°E and occupies an area of 50,778 square kilometers. Borno State is bordered by the Republic of Niger to the North, Chad to the North-east and Cameroon to the east [4].

2.2 Questionnaire Survey

Structured questionnaire was used to obtained socio-demographic data such as; age, occupation, information on duration of infertility, use of contraceptives, past history of STIs, educational status, knowledge about the *C. trachomatis* infection etc.

2.3 Sample size Determination

The sample size was determined using the formula;

$$\text{Minimum sample size (n)} = \frac{(z-e)^2(p)(q)}{d^2}$$

Where; n= minimum sample size,
(q)= 1-p, the confidence interval,
(p)= prevalence from literature found to be 8.7% =0.087 [5].
(d)= degree of freedom=5% (0.05)
(z)= the confidence coefficient from normal probability table (table E) to be ±1.96

Minimum sample size (n)

$$= \frac{(1.96)^2(0.087)(1 - 0.087)}{0.05^{\ 2}}$$

$$= \frac{(3.8416)(0.087)(0.913)}{0.0025}$$

= 122.05(approx. 122)

Minimum sample size (n) = 122

Margin of error is given as; E=$\frac{\frac{z\alpha}{2}}{\sqrt{n}}$ at 95% level of

confidence Where;
z= level of confidence (0.95)
α= 1-z, 1-0.95= 0.05
α/2= 0.05/2=0.025= 1.96 (from the table)
n= sample size as 122 from above

Therefore, error of margin E=$\frac{\frac{z\alpha}{2}}{\sqrt{n}}$

=1.96/2√122

= 0.0887 (0.0887×100)

= 8.87% margin of error

Therefore; 8.87% of 122 (sample size)

= 8.87÷100×122

= 10.82 (approx. 11)

Total sample size= 122+11= 133.

2.4 Inclusion and Exclusion Criteria

Infertile women (within the age of 18-47) attending fertility clinic of University of Maiduguri Teaching Hospital and post natal women within the same age group but attending post natal clinic of same Hospital were included in this study (as control subjects). Fertile women attending antenatal clinic and other women outside the aforementioned ones were excluded.

2.5 Sample Collection and Processing

This study was conducted between the months of October 2017 to May 2018. The endocervical swab (ECS) samples were collected from each subject's endocervix by using sterile swab after proper cleaning of the cervix with sterile swab to get rid of excess mucus. The samples were collected after obtaining an informed consent of each subject. During the collection process, the plug was removed from sterile tube and discarded. The Swab applicator was removed and specimen was collected by rotating the swab applicator against the wall of endocervical canal several times. The swab was withdrawn without touching the vaginal surface and the swab was inserted into the transport tube. Patient information was recorded in the space provided on the label and the specimen.

The specimens collected were processed using Chlamydia Rapid Test device (swab/urine) (Abon Biopharm (Hangzhou), Co., Ltd) an immunochromatographic technique for the detection of *Chlamydia trachomatis* antigen. In this test, antibody specific to the Chlamydia antigen is coated on the test line region of the test. During testing, the extracted antigen solution reacts with an antibody to Chlamydia that is coated onto particles. The mixture migrates up to react with the antibody to Chlamydia on the membrane and generates a colored line in the test line region. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a coloured line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

2.6 Statistical Analysis

Data generated from the study were analyzed using Statistical Package for Social Sciences (SPSS) version 21.0. Comparison of infertility and chlamydiasis was carried out by using independent sample t test, relationship between infertility and some associated risk factors were analysed by using Chi-square test. Distribution of *C. trachomatis* between infertile and post natal women were analysed by using one sample t test. A *P*-value ≤0.05 was considered significant at 95% confidence interval.

3. RESULTS AND DISCUSSION

A total of 65 subjects were enrolled in this study, out of these, 45 were infertile women (those with known history of primary or secondary infertility) while the remaining 20 were post natal women (fertile women). No single *Chlamydia trachomatis* was observed in both the study subjects (infertile and post natal women).

Result on the assessment of infertility based on age group, educational level and occupation are shown on Table 1. Highest number of infertility was observed on women within the age of 30-35 years (33.3%). On educational level, the result shows that those that attained tertiary educational level have the highest number of infertility (60%). Based on occupation, the study shows highest number of infertility among female civil servants (53.3%) followed by full-time house wife (33.3%).

Result on the assessment of infertility based on sexual practices, past pregnancies and miscarriages/abortion are shown in Table 2. Findings show highest number of infertility among women who partake in regular sex (86.7%). Highest number of infertility was observed among women who are not engaged in the use of contraceptive measures (95.6%). Findings also show the highest number of infertility among women who have not been pregnant before (75.6%). Result obtained from the study, also show that those that have no any histories of abortion or miscarriage have the highest number of infertility (84.4%). Results on the distribution of *C. trachomatis* among both infertile and post natal women are shown in Table 3. From the method of detection used in this study (Chlamydial rapid test device), no single *C. trachomatis* was detected from samples collected from all the subjects (infertile and post natal women).

Findings from this study show no relationship between *C. trachomatis* infection and infertility. This is contrary to the studies conducted in the United States that reported 5-15% prevalence of *C. trachomatis* infection among the infertile women [6]. In United States an approximately 4 million cases of Chlamydial infection are reported annually with an overall prevalence of 5% [7] and in Ethiopia 5.9% [3].

The study is also contrary to the reported 16% prevalence of *C. trachomatis* infection in UK among the infertile women [8]. Fourty percent (40%) prevalence was also reported in Jordan [9] and 22% prevalence was reported in Iran [10].

Two reports of *Chlamydial* infection prevalence among the infertile women in Lagos had a wide margin in their observations; 51% [11] and 18.2% [12]. Other reports from Jos, Zaria and Benin city all in Nigeria, show a prevalence rates of 51.6% [13], 40.7% [14,15] and 13.3% [16] respectively.

However, prevalence of chlamydial infection among the infertile females was reported to be 9.6% in Kano [5].

These observed differences could be related partly to the sensitivity and specificity of the rapid test kits used in this study, smaller sample size and to some extent the choice of single study area (University of Maiduguri Teaching Hospital, UMTH). Studies have reported the positive predictive value (sensitivity) and negative predictive value (specificity) of the test device used in this study as 91.8% and 100% respectively [17]. It could also be as a result of reduced sexual risk-behaviour among the subjects, increased awareness and other sexually transmitted diseases.

Studies have shown nucleic acid amplification tests and cell culture as the most sensitive procedure for the detection of *C. trachomatis* from the clinical specimens; however these procedures are unaffordable to an average Nigerian, hence the choice of the method used in this study (Chlamydia Rapid Test Device). This method is simple, has faster turnaround time and is affordable and had it been the method was found to be sensitive and specific, it would be recommended to be used in detecting early infection of *C. trachomatis* which would prevent the consequences of late infection which include but not limited to tubal factor infertility in female.

No single *C. trachomatis* was detected in all the subjects tested (both the infertile and post natal women), however, demographic and other details (age, educational background, occupation, sexual practices etc.) observed to have an association with infertility in females is in agreement with previous study [18].

Table 1. Assessment of infertility based on socio-demographic factors of the infertile women attending fertility clinic UMTH, Maiduguri

Variable	Number of infertile women examined (%)	Number of *Chlamydia trachomatis* positive (%)
Age group (years)		
18-23	02 (4.4)	00 (0.0)
24-29	14 (31.1)	00 (0.0)
30-35	15 (33.3)	00 (0.0)
36-41	13 (28.9)	00 (0.0)
42-47	01 (2.2)	00 (0.0)
Total	**45 (100.0)**	**00 (0.0)**
Educational level attained		
Primary	04 (8.9)	00 (0.0)
Junior secondary	01 (2.2)	00 (0.0)
Senior secondary	13 (28.9)	00 (0.0)
Tertiary	27 (60.0)	00 (0.0)
Total	**45 (100.0)**	**00 (0.0)**
Occupation		
Civil servant	24 (53.3)	00 (0.0)
Farmer	01 (2.2)	00 (0.0)
Trader	03 (6.7)	00 (0.0)
Student	02 (4.4)	00 (0.0)
Full-time house wife	15 (33.3)	00 (0.0)
Total	**45 (100.0)**	**00 (0.0)**
Total	**45 (100.0)**	**00 (0.0)**

Findings show no significant difference between infertility and Chlamydiasis by using independent sample t test (P>.05)

Table 2. Assessment of infertility based on sexual practices, past pregnancies and miscarriages/abortions of the infertile women attending fertility clinic UMTH

Variable	Number of infertile women examined (%)	Number of *Chlamydia trachomatis* positive (%)
How often do you engage in sex?		
Frequently	39 (86.7)	00 (0.0)
Not frequently	06 (13.3)	00 (0.0)
Total	**45 (100.0)**	**00 (0.0)**
Are you engaged in the use of any contraceptive measures?		
Yes	02 (4.4)	00 (0.0)
No	43 (95.6)	00 (0.0)
Total	**45 (100.0)**	**00 (0.0)**
Have you been pregnant before?		
Yes	11 (24.4)	00 (0.0)
No	34 (75.6)	00 (0.0)
Total	**45 (100.0)**	**00 (0.0)**
Have you had any miscarriage or an abortion before?		
Yes	07 (15.6)	00 (0.0)
No	38 (84.4)	00 (0.0)
Total	**45 (100.0)**	**00 (0.0)**

Findings show no significant relationship between infertility and the risk factors mentioned in the table by using Chi-square test (P>.05)

Table 3. Distribution of *Chlamydia trachomatis* among the infertile and post natal women attending fertility clinic in UMTH

Variable	Number examined	Infertile women	Post-natal woman
Age Groups (years)	Number Examined (%)	Number of Positive (%)	Number of Positive (%)
18-23	02 (4.4)	00 (0.0)	00 (0.0)
24-29	14 (31.1)	00 (0.0)	00 (0.0)
30-35	15 (33.3)	00 (0.0)	00 (0.0)
36-41	13 (28.9)	00 (0.0)	00 (0.0)
42-47	01 (2.2)	00 (0.0)	00 (0.0)
Total	**45 (100.0)**	**00 (0.0)**	**00 (0.0)**

*Findings show no significant difference in the distribution of C. trachomatis between infertile and post natal women by using one sample t test (P>.05)

4. CONCLUSION

No single *C. trachomatis* was detected in both test and control subjects (0.0%) by using Chlamydial Rapid Test Device. This may be attributed to the insufficient sensitivity of the test kit used, smaller sample size and or single study area used. However, the case of *C. trachomatis* infection may remain under diagnosed and continue to cause silent diseases in the apparently healthy populace of Maiduguri, Borno State, North-Eastern Nigeria.

5. RECOMMENDATIONS

Based on the findings from this study, the following recommendations were drawn:

1. More research should be conducted in the same area using different diagnostic techniques such as cell culture, nucleic acid amplification test, PCR based rapid diagnostic test, etc.
2. More subjects should be enrolled in the study; additionally more Hospitals should be included in the study to get to the root of the problem.
3. Awareness campaigns and chlamydia screening (using highly specific and sensitive test method) and monitoring activities should be initiated and supported by the government.

ETHICAL APPROVAL AND CONSENT

Ethical approval was obtained from the ethical committee, University of Maiduguri Teaching Hospital (UMTH). A written and verbal consent was required from the participants prior to the administration of the questionnaires. The subjects were informed that the results will be handled confidential and will not be known by anyone else.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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