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Research Article

Performance of Two Diagnostic Methods in the Detection of Gonorrhea Among Pregnant Women in Ogun State, Nigeria

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Abstract

The outcome of pregnancy is often threatened in the presence of sexually transmitted disease like gonorrhea which is common among pregnant women. This study was undertaken to investigate the performance of two diagnostic test methods in the screening of *Neiserria gonorrheae* infection among pregnant women in Ogun state. In total, hundred (100) pregnant women were recruited for this study. Endo-cervical swabs (ECS) were collected in pairs for the culture and RDT method. For the culture method, the swabs were plated on antibiotic incorporated chocolate agar plates to prevent growth of unwanted organisms. *Neisseria gonorrhea e* LabAcon rapid diagnostic test cassette supplied by Hangzhou Biotest Biotech Co., Ltd, China was used for the rapid screening. Conventional methods were used to identify *Neisseria gonorrheae* isolates, and disc diffusion was used to assess susceptibility to standard antibiotics using commercially made antibiotic discs. Out of the 100 participants, 12 (12%) tested positive to *N. gonorrheae* infection using the culture method and 7 (7%) out of which tested positive to *N. gonorrheae* infection when screened with the RDT kit. Screening using the culture method was more specific and sensitive than the RDT method. The isolates were most sensitive to Erythromycin, Ofloxacin, Ciprofloxacin, Azithromycin and Gentamycin and less sensitive to Tetracycline, Penicillin and Doxycycline. Lack of awareness of *Neisseria gonorrheae*, recent sexual intercourse, engagement in unprotected sex, number of sexual partners, and recent change in sexual partner were among the risk variables identified in this study as being connected with the occurrence of *N. gonorrheae* infection. The outcome of this study shows that gonorrhea is present among pregnant women receiving healthcare in BUTH and also gave credence to the superiority of Culture method (Gold standard) over RDT in the screening of gonorrhea.

Keywords: Gonorrhea; Pregnancy; Culture; Rapid Diagnostic Test Kits; Ogun State; Nigeria

Introduction

Gonorrhea, often known as the clap, is a bacterial infection of the genitourinary tract's mucous membranes caused by *Neisseria gonorrheae*, a Gram-negative diplococcus that is almost exclusively transmitted through sexual intercourse. Multiple mucosal locations in the lower female genital tract, including the urethra, cervix, Bartholin's and Skene's glands, as well as the anorectal canal, throat, and conjunctivae, may be involved in acquisition. It has the potential to spread to the upper vaginal canal, uterine tubes, abdominal cavity, and other organs [1].

Pregnancy, also known as gestation, is the period during which a woman's body develops one or more babies [2,3]. When a sexually transmitted disease, such as gonorrhea, is prevalent among pregnant women, the result of the pregnancy is frequently jeopardized. Early detection can help prevent future difficulties. In our setting, gonorrhea has been linked to a variety of obstetric and gynecological issues in pregnant women.

Infections with *N. gonorrhoeae* during pregnancy have been linked to a variety of negative pregnancy outcomes, including preterm labor, early membrane rupture, and uterine infections after delivery. Furthermore, after delivery, pregnant women might pass these diseases on to their babies [4]. Furthermore, pregnancy has been shown to hasten the progression of asymptomatic gonorrhea to symptomatic gonorrhea, which can lead to cervicitis and negative obstetric outcomes such as preterm delivery, low birth weight infants, and a higher rate of foetal mortality [5,6]. Pregnant women can also pass these diseases on to their babies after birth. For reducing newborn gonococcal infections, prenatal screening and treatment of pregnant women are critical [4-6].

The World Health Organization (WHO) estimates that 62 million cases of gonorrhea occur annually worldwide. Many infections in women, including gonorrhea, may not cause symptoms until they become problematic [7,8]. As a result, the CDC recommends that high-risk women be tested on a frequent basis, even if they show no symptoms. For reducing newborn gonococcal infections, prenatal screening and treatment of pregnant women are critical. Gonorrhea is the second most common sexually transmitted disease (STD), with females having greater rates than males. Because early infection might be asymptomatic and infection extension is typically accompanied with significant sequelae, gonorrhea affects women and newborns disproportionately. Screening is essential for identifying infections and preventing or limiting upper genital tract spread, as well as horizontal and vertical transmission [9]. All sexually active women at risk for infection, including those aged 25 and older who have had a previous gonorrhea infection, the presence of other sexually transmitted diseases, new or multiple sex partners, inconsistent condom use, commercial sex work, drug use, or human immunodeficiency virus (HIV) infection with sexual activity or pregnancy, should have their genital screening done once a year [4].

Sexual interaction with an infected person spreads gonorrhea. Oral, anal, and vaginal intercourse are all included. It can also be passed down from mother to kid during childbirth. The urine, urethra discharge (in males), or endocervical swab (in females) are required for diagnosis [10,11]. Infection with *Neisseria gonorrheae* can be detected using a culture, a rapid diagnostic test, or nucleic acid amplification techniques (NAATs). Unfortunately, the latter is prohibitively expensive, complex, and requires specialist knowledge. In contexts where laboratory diagnostic tools are unavailable, clinical diagnosis is frequently done based on the presence of symptoms such as vaginal and urethral discharge. The rapidly shifting antibiotic susceptibility patterns of *N. gonorrheae* complicate gonococcal infection therapy, increasing worries about the potential development of untreatable gonococcal infections with major sexual and reproductive health effects.

Many cases of gonorrhea are asymptomatic and hence may not require syndromic treatment. Only screening tests will be able to detect such situations. Culture is the gold standard test for detecting *N. gonorrheae*, and it has a high sensitivity and specificity. However, it takes a longer time and requires professional competence, compared to fast diagnostic procedures, which are relatively cheap, accessible, easy to conduct, and require little training. Sadly, these rapid diagnostic test kits frequently produce "false positive" or "false negative" results. As a result, it is necessary to compare their effectiveness to the gold standard of culture approach.

Furthermore, establishing baseline data is a vital epidemiological effort in reducing gonorrhea-related pregnancy problems. There is currently minimal information on the prevalence of gonorrhea among pregnant women in Ilishan-Remo Community of Ogun State. The aim of this study was to determine the performance of two diagnostic methods for the detection of *N. gonorrhea e,* its prevalence, as well as the antibiotic susceptibility patterns of *N.*

gonorrheae among pregnant women attending the Obstetrics and Gynecology Clinic of Babcock University Teaching Hospital.

Materials and Methods

Study design

This is an institutional based descriptive-epidemiological survey employing pregnant women without history of antibiotics, herbal remedies or any form of vaginal cream in the preceding two weeks before study commencement using an endocervical swab (ECS) specimen collected from each participant in duplicates by the attending health care personnel, one for the RDT and the second for culture purpose.

Study area

This study was conducted among pregnant women who visited the Babcock University Teaching Hospital's (BUTH) Obstetrics and Gynecology clinic in Ilishan-Remo, Ogun State. BUTH is a 300-bed private hospital that serves as the community's only tertiary care facility. While the Ilishan-Remo community is a geopolitical ward in the Ikenne Local Government Area of Ogun State, which is located in the tropical area of Nigeria's south-western region at 7o29'00"N, 2o55'00"E.

Duration of study

The research was carried out between March and May of 2020.

Sample size calculation

The sample size (n) was estimated using the single population proportion formula described by Charan and Biswas [12]:

$N = Z^2PQ/d^2$

Where;

N = Required sample size,

Z = Standard normal variate at 5% ($p < 0.05$) error or 95% confidence interval is 1.96

P = Proportion of the population with *Neisseria gonorrheae* infection from previous study,

Q = Proportion of the population without *Neisseria gonorrheae* infection (1- P) and

d = Absolute error margin is 0.05.

For the calculation, a 95% confidence interval, a P value of 0.07. i.e., a prevalence rate of 7% from a previous study by Olalekan and Owobi [13] and margin error (d) set at 0.05 will be used to determine the minimum sample size required.

$N = Z^2PQ/d^2$

$N = 1.96^2 \text{ X } 0.07 \text{ X } 0.93/0.05^2$

$N = 3.8416 \text{ X } 0.07 \text{ X } 0.93/0.0025$

$N = 3.8416 \text{ X } 0.07 \text{ X } 0.93/0.0025$

$N = 0.2501/0.0025$

$N = 100.04 \approx 100.$

Sample size

A total of 100 endocervical swab (ECS) specimens were obtained at random from 100 pregnant women attending the Babcock University Teaching Hospital's Obstetrics and Gynecology Clinic in Ilishan-Remo, Ogun state.

Informed consent

Each consenting participant whose endocervical swab samples was used in the study gave their informed consent. The participants were informed about the study's goals, benefits, and procedures, and they were ensured of the study's confidentiality and voluntariness.

Data collection

Prior to the collection of the specimens, the participants' demographic and clinical information were gathered using prepared questionnaires that were given to them. A unique participant identification number (PIDN) was assigned to each questionnaire. In the study location, data collection lasted an average of 7 days. The subjects were chosen, questionnaires were distributed and retrieved, and samples were collected during this time. The subjects were given the pre-test questionnaires directly. The participants' bio data, such as age, marital status, and tribe, were included in the first section of the questionnaires. The second section contained clinical information about gonorrhea history (abnormal, foul smelling vaginal discharge, vaginal itching, etc.). Every day, all completed questionnaires were checked for accuracy and stored safely in a locker. The data entry was completed the next day. Only the PIDN was recorded for each participant.

Collection of endocervical swab

The endocervical swab (ECS) specimen was collected from each participant in duplicates by the attending health care personnel, one for the RDT and the second for culture purpose. Briefly, each participant was placed in the lithotomy position, draped appropriately and instructed to take deep breaths. Using gloved hands, the attending health care personnel inserted a sterile disposable cervical speculum that has been lubricated with warm water. Excess mucus were removed from the exocervix using a cotton ball in ring forceps. A sterile swab was then removed from its protective transport tube and held firmly by the handle and inserted into the endocervical canal about 1-2 cm and rotated firmly for about 15-30 seconds. The swab was withdrawn without touching any of the vaginal surfaces and then inserted back into the tube screwing it tightly for collection.

Specimen storage

Specimens were processed as soon as they were received. When there was a chance of a delay, they were maintained in the refrigerator at 2-8°C until the analysis was completed.

Laboratory analysis

The two methods were employed for the detection of *N. gonorrhea* e in this study: Rapid diagnostic test (RDT) and culture method.

Detection of *Neisseria gonorrheae* antigen using rapid diagnostic test kit

Neisseria gonorrheae antigen was detected using Gonorrhea rapid test Cassette supplied by Hangzhou Biotest Biotechnology Company, Limited, China according to the manufacture instruction.

Principle

Gonorrhea rapid test kit is a rapid chromatographic immunoassay for the qualitative detection of the *Neisseria gonorrheae* antigen in female High vaginal swab specimens to aid in the diagnosis of Gonorrhea infection. In the test, antibody specific to the Gonorrhea antigen is coated on the test line region of the test. During testing, the extracted antigen solution reacts with an antibody to Gonorrhea that is coated onto particles. The mixture migrates up to react with the antibody to Gonorrhea on the membrane and generates a colored line in the test 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 colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Procedure

Briefly, all materials and specimen were brought to room temperature (15-30°C) prior to testing. 300 µl (about 6 drops) of Buffer A solution was added from bottle into the mixing tube. The swab with the specimen were inserted into the mixing tube, and twirled briefly to mix the specimen into the solution. The swab was kept immersed for 5 minutes. 300 µl (about 6 drops) of Buffer B solution was added from the bottle into the mixing tube. Equal volume of Buffer B was added to Buffer A. The swab was twirled vigorously for 10 seconds to mix the solution well. The swab was removed and discarded. The mixing tube was caped and the contents mixed by gently swirling the tube. The testing cassette was removed from the foil pouch and placed on a level surface. Using a micropipette, 100 µl (about 4 drops) of solution was drawn from the mixing tube and dispensed into the well of the test cassette. The result was read at 15 minutes and observed for color band. The test device was discarded after single use in the dustbin. Results read after 20 minutes was considered not valid.

Interpretation of test

Positive (+) result

Two rose-pink bands appear at "C" and "T". The sample is considered positive for Gonorrhea.

Negative (-) result

Only one rose-pink band appears at "C". The sample is considered negative for Gonorrhea.

Invalid result

No visible band at all or there is a visible band only at "T", but not at "C". The test was repeated with a new test kit.

Detection of *Neisseria gonorrheae* using culture Method

The endocervical swab sticks were streaked on Chocolate agar plates, as well as Thayer-Martin agar plates selective for *N. gonorrheae* and was incubated anaerobically at 37°C for 18-24 hours.

Identification of bacterial isolates

For the identification of the bacterial isolates, standard procedures (macroscopy and microscopy) were used. Size, shape, texture, elevation, coloration, border, and opacity were all examined and recorded as morphological characteristics of the colonies. To demonstrate their forms and organization, the Gram staining technique was used. Catalase, oxidase, and triple sugar iron tests were used to assess their biochemical features as a form of confirmation [14].

Determination of the antibiotic sensitivity pattern of *Neisseria gonorrheae* isolates

We used the modified Kirby-Bauer disc diffusion technique as described by Cheesbrough [15] and CLSI [16] to assess the antibiotic sensitivity pattern of *Neisseria gonorrheae*. The antibiotic Discs to be used include: Ofloxacine (10 ug), Peflacine (10 ug), Ciprofloxacine (5 ug), Augumetine (30 ug0, Gentamicin (10 ug), Streptomycin (30 ug), Sulphamethazole/Trimethoprim (30 ug), Ampicillin (30 ug), Cephalexin (30 ug) and Nalidixic acid (30 ug) supplied by Optum Lab Nigeria. Commercially prepared antibiotic disc of known concentration is placed onto the surface of a plate of sensitivity testing agar uniformly inoculated with the test organism. The antibiotic agent diffuses through the agar resulting in a concentration gradient. Diffusion through the agar is based on many factors including the molecular size of the antibiotic agent and agar concentration of the medium. The growth of the test organism is inhibited at a distance from the disc depending on the sensitivity of the organism. Strains sensitive to the antibiotic are inhibited at distance from the disc whereas resistant strains have smaller zones of inhibition or grow up to edge of the disc.

Statistical analysis

Microsoft Excel was used to enter the raw data. The SPSS statistics software package was used to conduct the statistical analysis (version 18.0). The data was examined statistically using Chi-square and Tukey-Kramer multiple comparisons tests to see if there were any significant variations in the prevalence of gonorrhea between the RDT and culture methods among the study participants. The significance threshold was determined to be 95%. The Wilson's score method was used to calculate the confidence intervals for the sensitivity and specificity of the two screening methods. P values of less than 0.05 were considered significant. Tables and charts were used to present the results of the statistical analysis.

Results

The current study used the Rapid Diagnostic Test (RDT) and Culture technique to determine the prevalence of *Neiserria gonorrhea* infection among pregnant women attending Babcock University Teaching Hospital in Ilishan Remo, Ogun State, Nigeria. A total of 100 patients were screened for *Neiserria gonorrheae* as part of the investigation. Table 1 shows the demographic characteristics of the study participants, such as age, marital status, religion, tribe, and gestational period. The majority of the participants (30%) were between the ages of 28 and 37years, while the minority were between the ages of 18 and 27years (20%). Sixty percent (60%) of those who took part in the study were married, 20% were single, and 20% were separated. Based on their gestational period, Majority of them were in their second trimester (55%), followed by those in their first trimester (35%) and the rest were in their third trimester (10%).

Table 1: Demographic characteristics of the study participants

Characteristics	Category	Number (N)	Percentage N (%)
Age range (Yrs)	18-27	20	20 (20)
	28-37	30	30 (30)
	38-47	25	25 (25)
	≥48	25	25 (25)
	Total	100	100 (100)
Marital status	Single	20	20 (20)
	Married	60	60 (60)
	Separated	20	20 (20)
	Total	100	100 (100)
Religion	Christianity	95	95 (95)
	Islam	5	5 (5)
	Traditional	0	0 (0)
	Others	0	0 (0)
	Total	100	100(100)
Tribe	Yoruba	80	80 (80)
	Igbo	15	15 (15)
	Hausa	5	5 (5)
	Others	0	0 (0)
	Total	100	100 (100)

Gestational period	First trimester	35	35 (35)
	Second trimester	55	55 (55)
	Third trimester	10	10 (10)
	Total	100	100 (100)

The percentage occurrence of *Neisseria gonorrheae* positivity among the study participants by Culture and Rapid Diagnostic Test Methods is presented using a Pie chart (Figure 1). Out of the 100 participants screened for *Neisseria gonorrheae* infection, twelve (12%) participants tested positive to *N. gonorrheae* by culture method, while seven (7%) tested positive to *N. gonorrheae* infection using Rapid Diagnostic Test Kit.

Figure 1: A pie chart showing percentage occurrence of *Nesserria gonorrheae* positivity by Culture and Rapid Diagnostic Test Methods.

Table 2 shows the frequency of *Neisseria gonorrhoeae* infection in relation to the socio-demographic features of the study participants using culture method. According to the age distribution of *Neisseria gonorrheae* infection, the majority of those who tested positive by culture method were between the ages of 28 and 37 (6%), while the fewest were between the ages of 38 and 47 (1%). The largest prevalence was observed among married women (8%), while the lowest occurrence was found among singles (4%). Yoruba (10%) and Igbo (2%) individuals had the highest and lowest occurrences, respectively, based on tribe. There were none (zero percent) in other tribes. Based on gestational period, the highest occurrence was found among women in their first and second trimester (5% each), while the least participants were in their third trimester (2%). There was no statistical significant difference in the occurrence of *N. gonorrheae* infection among the study participants using culture method on the basis of their age, marital status, tribe and gestational period ($p > 0.05$).

Table 3 shows the frequency of *Neisseria gonorrheae* infection as measured by the rapid diagnostic test method in relation to the socio-demographic features of the study participants. Based on age distribution of *Neisseria gonorrheae* infection, most of them who tested positive by culture method were in the age range 28-37 years (4%), while the least were in the age range of ≥48 years (1%). Based on marital status, 5% of those positive for *Neisseria gonorrheae* using RDT were married, while 2% were singles. Based on tribe, the highest and lowest occurrence was found among the Yoruba (6%) and Igbo (1%) participants, respectively. None (0%) was recorded in other tribes. Based on their gestational period, he highest occurrence was recorded among women in their second trimester (3%) followed by those in their first and third trimester (2% each). There was no significant statistical difference ($p > 0.05$) in the frequency of *N. gonorrheae* using RDT on the study participant on the basis of their marital status, age, tribe and gestational period.

The distribution of symptomatic and asymptomatic of *Neisseria gonorrheae* infection is presented using a bar chats in (Figure 2). Out of the twelve (12%) participants that tested positive, seven (7%) participants were symptomatic, while five (5%) were asymptomatic with *Neisseria gonorrheae* infection and eighty-eight (88%) tested negative.

Table 2: Frequency of occurrence of *Neisseria gonorrheae* infection using culture method in relation to the socio-demographic characteristics of the study participants.

Characteristics	Number of cervical swabs examined	Number positive N (%)	Number negative N (%)	P-Value	Pearson Chi-Square (X^2)
Age range (Yrs)					
18-27	20	3 (3)	17 (17)	3.532	0.317[a]

28-37	31	6 (6)	25 (25)		
38-47	24	1 (1)	23 (23)		
≥48	25	2 (2)	23 (23)		
Total	100	12 (12)	88 (88)		
Marital status					
Single	20	4 (4)	16 (16)	4.040	0.133[a]
Married	60	8 (8)	52 (52)		
Separated	20	0 (0)	20 (20)		
Total	100	12 (12)	88 (88)		
Religion					
Christianity	95	10 (10)	85 (85)	3.907	0.048[a]
Islam	5	2 (2)	3 (3)		
Traditional	0	0 (0)	0 (0)		
Others	0	0 (0)	0 (0)		
Total	100	12 (12)	88 (88)		
Tribe					
Yoruba	80	10 (10)	70 (70)	0.726	0.696[a]
Igbo	15	2 (2)	13 (13)		
Hausa	5	0 (0)	5 (5)		
Others	0	0 (0)	0 (0)		
Total	100	12 (12)	88 (88)		
Gestational period					
First trimester	34	5 (5)	29 (29)	1.075	0.584[a]
Second trimester	55	5 (5)	50 (50)		
Third trimester	11	2 (2)	9 (9)		
Total	100	12 (12)	88 (88)		

P > 0.05 is considered statistically not significant.

Table 3: Frequency of occurrence of *Neisseria gonorrheae* infection using Rapid Diagnostic Test method relation to the socio-demographic characteristics of the study participants.

Characteristics	Number of cervical swabs examined	Number positive N (%)	Number negative N (%)	P-Value	Pearson Chi-Square (X^2)
Age range (Yrs.)					
18-27	20	2 (2)	18 (18)	0.252	4.088[a]
28-37	31	4 (4)	27 (27)		
38-47	24	0 (0)	24 (24)		
≥48	25	1 (1)	24 (24)		
Total	100	7 (7)	93 (93)		
Marital status					
Single	20	2 (2)	18 (18)	0.378	1.946[a]
Married	60	5 (5)	55 (55)		

Separated	20	0 (0)	20 (20)		
Total	100	7 (7)	93 (93)		
Religion					
Christianity	95	6 (6)	89 (89)	0.242	1.366[a]
Islam	5	1 (1)	4 (4)		
Traditional	0	0 (0)	0 (0)		
Others	0	0 (0)	0 (0)		
Total	100	7 (7)	93 (93)		
Tribe					
Yoruba	80	6 (6)	74 (74)	0.815	410[a]
Igbo	15	1 (1)	14 (14)		
Hausa	5	0 (0)	5 (5)		
Others	0	0 (0)	0 (0)		
Total	100	7 (1)	93 (93)		
Gestational period					
First trimester	34	2 (2)	32 (32)	0.304	2.380[a]
Second trimester	55	3 (3)	52 (52)		
Third trimester	11	2 (2)	9 (9)		
Total	100	7 (7)	93 (93)		

P > 0.05 is considered statistically not significant.

Figure 2: The distribution of symptomatic and asymptomatic of *Neisseria gonorrheae* infection.

Indication for gonorrhea in relation to *N. gonorrheae* positivity by RDT and Culture method among study participants is presented in table 5. Out of twenty (20) participants who indicated vaginal itching, four (4) tested positive to *N. gonorrheae* using RDT, while seven (7) tested positive by culture method. Out of fifteen (15) participants that indicated vaginal discharge, six (6) tested positive to *N. gonorrheae* by RDT method while eight (8) tested positive by culture method. Out of seven participants that indicated genital lesion, two (2) tested positive to *N. gonorrheae* by RDT method while five (5) tested positive by culture method. No participant indicated genital ulcer.

Tables 6 and 7 show the risk factors for *Neisseria gonorrheae* infection among study participants who were screened using RDT and culture methods. Identified risk factors includes: awareness of *Neisseria gonorrheae* (OR, 1.833, 1.800, respectively), recent sexual intercourse (OR, 1.541,1.286, respectively), engagement in unprotected sex (OR, 0.235, 0.500, respectively), number of sexual partner (OR, 0.926,0.874, respectively), and recent change in sexual partners (OR, 0.922,0.867, respectively) among others, but none was found to be significantly associated with the occurrence of *Neisseria gonorrheae* among the study participants (p > 0.05).

Antibiotic susceptibility pattern of *Neisseria gonorrheae* isolates recovered among the study participant are presented

Table 4: Indication for gonorrhea in relation to *Neisseria gonorrheae* positivity by RDT and Culture method among the study participants.

Sign and Symptoms	Response	RDT Result			Culture Result		
		Negative	Positive	Total	Negative	Positive	Total
Vaginal itching	No	77	3	80	75	5	80
	Yes	16	4	20	13	7	20
Vaginal discharge	No	84	1	85	81	4	85
	Yes	9	6	15	7	8	15
Genital lesion	No	88	5	93	86	7	93
	Yes	5	2	7	2	5	7
Genital ulcer	No	93	7	100	88	12	100
	Yes	0	0	0	0	0	0

using a histogram (Figure 3). A total of 12 isolates were tested for their antibacterial sensitivity pattern. All the isolates (100%) were sensitive to Erythromycin, Ofloxacin, Ciprofloxacin, Azithromycin, and Gentamycin. Ten isolates (83.3%) were sensitive to Cefotaxime and six isolates (50%) were sensitive to Co-trimoxazole, whereas all the isolates (100%) were resistant to Tetracycline, Penicillin and Doxycycline. Meanwhile, 6 isolates (50%) were resistant to Co-trimoxazole and 2 (16.7%) were resistant to Cefotaxime.

Table 5: Risk factors associated with the occurrence of *Neisseria gonorrheae* infection among study participants screened using RDT method.

Characteristics	Responses	Total	Negative (%)	Positive (%)	X^2	P-value	Odd ratio
Awareness of STD	No	29	30	1	0.885	0.347	2.719
	Yes	64	70	6			
Awareness of *Neisseria gonorrheae*	No	66	70	4	0.592	0.441	1.833
	Yes	27	30	3			
Recent sexual intercourse	No	19	20	1	0.154	0.695	1.541
	Yes	74	80	6			
Share underwear/pants with others	No	88	95	7	0.396	0.529	0.926
	Yes	5	5	0			
Frequency in changing of under-wear	Every 2 days	5	5	0	0.396	0.529	1.080
	Everyday	88	95	7			
Engagement in unprotected sex	No	8	10	2	2.884	0.089	0.235
	Yes	85	90	5			
Number of sexual partner	1-2	88	95	7	0.396	0.529	0.926
	3-5	5	5	0			
Recent change in sexual partners	No	83	90	7	0.836	0.360	0.922
	Yes	10	10	0			
Frequency of sexual intercourse per week	3-5	12	14	2	1.327	0.249	0.370
	1-2	81	86	5			
Frequency in the use of contraceptives	No	88	95	7	0.396	0.529	0.926
	Yes	5	5	0			
Frequency in the use of sanitary facilities with others	No	27	30	3	0.592	0.441	0.545
	Yes	66	70	4			

P > 0.05 is considered statistically not significant.

Table 6: Risk factors associated with the occurrence of *Neisseria gonorrheae* infection among study participants screened using Culture method.

Characteristics	Responses	Total	Negative (%)	Positive (%)	X^2	P-value	Odd ratio
Awareness of STD	No	30	27	3	0.162	0.687	1.328
	Yes	70	61	9			
Awareness of *Neisseria gonorrheae*	No	70	63	7	0.884	0.347	1.800
	Yes	30	25	5			
Recent sexual intercourse	No	20	18	2	0.095	0.758	1.286
	Yes	80	70	10			
Share underwear/pants with others	No	95	84	11	0.319	0.572	1.909
	Yes	5	4	1			
Frequency in changing of underwear	Every 2 days	5	5	0	0.718	0.397	1.145
	Everyday	95	83	12			
Engagement in unprotected sex	No	10	8	2	0.673	0.412	0.500
	Yes	90	80	10			
Number of sexual partner	1-2	95	83	12	0.718	0.397	0.874
	3-5	5	5	0			
Recent change in sexual partners	No	90	78	12	1.515	0.218	0.867
	Yes	10	10	0			
Frequency of sexual intercourse per week	3-5	14	12	2	0.081	0.777	0.789
	1-2	86	76	10			
Frequency in the use of contraceptives	No	95	83	12	0.718	0.397	0.874
	Yes	5	5	0			
Frequency in the use of sanitary facilities with others	No	30	26	4	0.072	0.788	0.839
	Yes	70	62	8			

$P > 0.05$ is considered statistically not significant.

Figure 3: A histogram showing the antibiotic susceptibility pattern of *Neisseria gonorrheae* isolates recovered among the study participants.

The Sensitivity, Specificity and Predictive values of rapid diagnostic test method is presented in Table 8. Seven (7) participants were truly positive (TP), five (5) participants were falsely positive (FP), seventy-eight (78) were truly negative (TN), none (0) was falsely negative. Meanwhile the method had 100% sensitivity, 94.6% specificity, 58.3% Positive predictive value (PPV) and 100% Negative Predictive value (NPV).

Table 7: Sensitivity, Specificity and Predictive values of rapid diagnostic test method.

	TP (NO)	FP (NO)	TN (NO)	FN (NO)	Se (%)	Sp (%)	PPV (%)	NPV (%)
RDT	7	5	78	0	100	94.6	58.3	100

Keys: Se = Sensitivity (TP/TP+FN) is the percentage of patients with the disease who are appropriately recognized as positive by the test. Sp = Specificity (TN/FN+TN), which is the fraction of individuals without the disease accurately recognized as negative by the test, it is the probability that a sick individual will have a positive test. PPV = Positive predictive value (TP/TP+FP), which is the fraction of those with positive tests who truly have the condition, it is the chance that a healthy person will have a negative test. NPV = Negative Predictive Value (TN/FN+TN), which is the fraction of people with negative tests who do not have the condition, it is the probability that those who have a positive test are actually sick. TP = Truly Positive, and it refers to test results that are positive for those who are healthy. FP = False Positive, and refers to test findings that are positive for people who are not unwell. TN = Truly Negative (test results that are negative for those who are healthy), FN = False Negative, test results that are negative for those who are sick, No = Number, % = percentage.

Figure 4: LabAcon RDT Cassette negative for *Neisseria gonorrheae*.

Figure 5: LabAcon RDT Cassette positive for *Neisseria gonorrheae*.

Discussion

Gonorrhea is the second most commonly reported sexually-transmitted disease (STD) and rates are higher among women than men [4,5]. The 12% prevalence rate observed in this study using culture method was higher than the 1.3%, 2.0%, 7% and 7.2% reported by Aboyeji and Nwabuisi [17], Nsofor., *et al*. [18], Olalekan., *et al.* [13], and Bassey., *et al*. [19], respectively, in a study carried out among women attending different clinics in Nigeria (Ilorin, Owerri, Abuja, Kubwa, respectively). With regards to the use of rapid diagnostic kit in the screening of women, the 7% Observed in this study was slightly higher than the 5% reported by Wariso *et al*. [20] among undergraduate female students attending the University of Port-Harcourt, Southern-Nigeria using the strand displacement amplification (SDA) technique, another type of rapid diagnostic method, but molecular in nature. It is important to note here that to the best of our knowledge, this study is the first to report the use of *Neisseria gonorrheae* cassette test kit for the screening of gonorrhea among pregnant women in Ogun State.

According to Clark., *et al.* [21], gonococcal infections were noted to be most prevalent in the group aged 20-24 years (34.09%) in a study carried out among women in Bacolod City, Philippines. This does not agree with the outcome of this study, with the most prevalence rate in the age range of 28-37 years (30%). The reason for this disparity is unclear; however, it may be attributed to the improved lifestyle adults are currently adopting. Meanwhile it was comparable to studies done by Bassy., *et al.* [19] in female patients attending clinics in Kubwa-Abuja, Nigeria.

The level of occurrence of marital status, recorded by Bassy., *et al.* [19] was higher in singles ladies (8.3%) followed by married women (1.7%) which is different from what was gotten in this study with the highest occurrence being among married women (60%) followed by single and separated women (20%). The reason for this difference may not be unconnected to the sample size, as well as the category of subjects recruited for the study.

The prevalence of symptomatic *Neisseria gonorrheae* infection among study participants was observed to be greater than asymptomatic ones. In this study, we defined symptomatic *Neisseria gonorrheae* infection as the presence of one or more signs and symptoms associated with gonorrhea infection and the identification of *Neisseria gonorrheae* in the endo-cervical swab culture of the participants. Asymptomatic *Neisseria gonorrheae* infection, on the other hand, is defined as the discovery of *Neisseria gonorrhea* species in the study participants' endo-cervical swab culture in the absence of one or more signs and symptoms consistent with *Neisseria gonorrheae* infection.

In terms of the symptoms of *Neisseria gonorrheae* infection (vaginal itching, vaginal discharge, vaginal lesion, vaginal ulcer, etc.) and the prevalence of *Neisseria gonorrheae*, it appears that these symptoms were more prevalent among married women. This suggests that they contracted *N. gonorrheae* from one of their partners who contracted it elsewhere. In a study conducted in Melbourne, Australia, Maddaford., *et al*. [22] reported symptoms such as abnormal vaginal discharge (39.2%), which is higher than the 6% reported in this study, vaginal itching (2.7%), and vaginal lesion (1.4%), which are slightly lower than the 4 percent and 2 percent reported in this study, respectively. The outcome of this study is also comparable to that of Uwakwe., *et al.* [23] carried out in Imo State, Nigeria among pregnant women with abnormal vaginal discharge which reported 55.6%, all within the age range of 21-30 years which is higher than the 14% reported in this study.

Furthermore, the appearance of vaginal discharge, irritation, a vaginal ulcer, or a vaginal lesion does not necessarily indicate that the person is infected with *Neisseria gonorrheae*. The explanation for this is simple: pathogens other than *Neisseria gonorrheae*, such as viruses (e.g., Herpes simplex virus, Human papilloma virus, and Human immunodeficiency virus), bacteria (e.g., Chlamydia spp., *Treponema pallidium*), and parasites (e.g., *Trichomonas vaginalis*) [24] have been implicated to cause such discomforts.

For this reason, differential diagnosis is crucial in determining the true causal agent of infection when symptoms are identical. Wrong diagnosis can lead to wrong treatment. Antimicrobial resistance is mostly due to over-the-counter drugs purchases made without proper laboratory test findings, which clinicians are presently addressing [25].

Furthermore, recent changes in sexual partners, having several sexual partners, and not cleaning the vulva before or after sexual intercourse, among other factors, can all contribute to *Neisseria gonorrheae* infection. Because unprotected sex can spread the infection from one person to another by contact with an infected individual's body fluids during sexual intercourse, condom use is recommended [26].

The antibacterial susceptibility pattern of *Neisseria gonorrhea*e isolates observed in this study was close to that of Clark., *et al.* [21], who studied *Neisseria gonorrheae* isolates in Bacolod City, Philippines. Ceftriaxone, with a sensitivity of 100 percent, is still the most effective drug, followed by Spectinomycin and Cefixime, which have sensitivity of 92.1% and 80.9%, respectively. The most inefficient antibiotic was penicillin G, which had 100 percent resistance, followed by ciprofloxacin and tetracycline, which had 4.9 percent and 5.1 percent resistance, respectively. Meanwhile, with a sensitivity of 100 percent, Erythromycin, Ofloxacin, Ciprofloxacin, Azithromycin, and Gentamycin were the most effective drugs in this study, followed by Co-trimoxazole (50%).

Conclusion

In conclusion, screening for *Neisseria gonorrheae* infection using the rapid diagnostic method (RDT) is as sensitive as using the culture method but is less specific. This gives credence to the superiority of culture method (Gold standard) over RDT. However, in resource-limited settings, rapid diagnostic test kits can easily be deployed for quick diagnosis of gonorrhea for early treatment. However, where facility for culture method is available, it can be used in addition to the RDT for confirmatory diagnosis.

Ethical Approval

Ethical approval for the study was obtained from the Babcock University Health Research Ethics Committee (BUHREC) with ethical approval registration number: BUHREC 213/20.

Competing Interests

Authors have declared that no competing interests exist.

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