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Original Research Article

Study of the frequency of female genital tract infection using cartridge based nucleic acid amplification test

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ABSTRACT

Background: The aim of the study was to study the frequency of female genital tract infection using cartridge based nucleic acid amplification test (CBNAAT), to study the sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of CBNAAT.
Methods: This prospective observational study was conducted among 100 patients as per inclusion criteria with genital tract infection in Swami Vivekanand Subharti University, Meerut over a period of two years. Investigations including ZN staining for acid fast bacillus (AFB), endometrial sampling for histopathology, CBNAAT and BACTEC culture were sent.
Results: In a study of 100 patients' histopathological examination detected tuberculosis in 2% patients while CBNAAT detected tuberculosis in 5% patients. Tubercle bacilli was found in 3% women on AFB stain while in only 1%-woman genital tuberculosis was diagnosed by BACTEC culture.
Conclusions: Female genital tuberculosis is detected most frequently when a woman presents with unexplained infertility. Newer technologies allow genital tuberculosis to be identified at an earlier stage and enable us to provide treatment. CBNAAT being a sensitive test picked up more cases than histopathology, culture, AFB stain. Hence CBNAAT should be widely used for early detection of female genital tuberculosis.

Keywords: CBNAAT, Tuberculosis, Tubercle bacilli

INTRODUCTION

Tuberculosis (TB) is one of the oldest diseases as old as human civilization.[1] It is a chronic infectious disease and the morbidity associated with this condition has major health implications.[2] Throughout the world tuberculosis affects about 9.4 million people annually with about two million deaths.[3,4] Apart from commonest and the most infectious pulmonary TB, extra pulmonary TB (EPTB) is being increasingly encountered throughout the world.[5] Female genital TB (FGTB) is an important cause of significant morbidity, short-and long-term sequelae especially infertility.[5-8] Genital TB is mostly secondary to pulmonary TB or extrapulmonary foci. The genital organs affected by *Mycobacterium tuberculosis* (in descending order of frequency) are as follows: fallopian tubes (95-100%), uterine endometrium (50-60%), ovaries (20-30%), cervix (5-15%), uterine myometrium (2.5%) and vagina/vulva (1%).[9] CBNAAT is a semi quantitative real time PCR for both mycobacterium tuberculosis (MTB) as well as detecting genetic mutations associated with the resistance to the drug rifampicin. CBNAAT by virtue of using 3 primers and 5 probes is a completely automated highly specific test with metanalysis of literature reporting sensitivity at 90.4% and specificity of 98.4% in pulmonary TB identification.[10]

METHODS

This prospective observational study was conducted among all OPD and IPD suspected patients of genital tract

infection of Subharti medical college, Meerut, over a period of two years.

An ethical clearance was approved by the institutional review board for ethical clearance of the institution (Subharti medical college).

Sample size was 100 and calculated by $n=z^2pq/d^2$

On calculation "n" was equal to 125.79, which was rounded off to 126.

Inclusion criteria

All OPD and IPD patients were included in the study.

Exclusion criteria

Pregnancy and pregnancy related problems, patient on ATT, infertile women with known male factor infertility and immunocompromised patients were excluded from the study.

A detailed history regarding current complaints of the patient, age, menstrual and gynecological history, family history and past history of tuberculosis and history of any treatment was undertaken. A systemic and gynecological examination was done. Investigations which include ZN staining for AFB, endometrial sampling for histopathology, CBNAAT and BACTEC culture were sent after taking written and informed consent for participation in the study. Endometrial samples were obtained by gentle aspiration or curettage using Karmann's cannula under paracervical block. One part of biopsy was subjected to histopathological examination (in formalin) and second part was sent to lab for CBNAAT, culture media and AFB stain (in normal saline).

Statistical analysis

Data was analyzed using SPSS software version 24. Sensitivity, specificity, positive predictive value and negative predictive value was calculated.

RESULTS

Out of 100 women maximum were from the age group of 21-30years (Table 1). histopathological examination (HPE) detected tuberculosis in 2(2%) patients while CBNAAT detected tuberculosis in 5 (5%) patients. Tubercle bacilli was found in 3 (3%) women on AFB stain while in only 1 (1%) woman genital tuberculosis was diagnosed by BACTEC culture. Sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of CBNAAT considering HPE as gold standard was 100%, 97.03%, 99.84%, 100% and 99.85% of the subjects respectively (Table 2). Sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of CBNAAT considering AFB stain as gold standard was 100%, 97.89%, 99.89%, 100% and 99.89% of the subjects respectively (Table 3). Sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of CBNAAT considering culture as gold standard was 100%, 95.96%, 99.79%, 100% and 98.80% of the subjects respectively (Table 4).

Table 1: Distribution of women according to age.

Age group (years)	N	Percentage (%)
21-30	61	61
31-40	32	32
>40	7	7
Total	100	100

Table 2: Diagnostic efficacy of CBNAAT considering HPE as gold standard.

Variables		CBNAAT		Total
		+ve	-ve	
HPE	+ve	2	0	2
	-ve	3	95	98
Total		5	95	100

Table 3: Diagnostic efficacy of CBNAAT considering AFB stain as gold standard.

Variables		CBNAAT		Total
		+ve	-ve	
AFB stain	+ve	3	0	3
	-ve	2	95	97
Total		5	95	100

Table 4: Diagnostic efficacy of CBNAAT considering BACTEC culture as gold standard.

Variables		CBNAAT		Total
		+ve	-ve	
Culture	+ve	1	0	1
	-ve	4	95	99
Total		5	95	100

DISCUSSION

Out of 100 subjects, maximum subjects were from the age group of 21-30 years. Garg et al in their study too revealed that maximum patients were from age group 26-30 years (43.20%).[11] In our study 8% women gave history of some family member suffering from tuberculosis. In a study by Arpitha et al 11.1% patients had a previous history of extra genital TB.[13] In our study 10% women had complaint of heavy menstrual bleeding while 11% had reduced menstrual flow, 25% women had delayed cycles and 7% women complained of amenorrhoea, whereas 13% women complained of dysmenorrhoea. Similar findings were reported in a study by Sharma where normal menstrual pattern was seen in 57.6% of patients and most common menstrual abnormality was hypomenorrhoea in 30.1% followed by oligomenorrhoea in 3.5%.[12] In our study, 3

women showed evidence of endometritis on HPE, 2% women among them had tuberculous endometritis while only 1% had nonspecific endometritis. Of the remaining 97 women, 38% had proliferative endometrium and 59% women had secretory endometrium. In 2018 a study was conducted by Garg et al on GeneXpert test and endometrial histological findings in infertile women.[11] In this study secretory endometrium was found in 55.55% cases, proliferative endometrium (anovulatory) in 41.9% cases, non-specific endometritis in 1.23% case.However in our study due to COVID, we were able to recruit 100 subjects.

CONCLUSION

Female genital tuberculosis is detected most frequently when a woman presents with unexplained infertility. Newer technologies allow genital tuberculosis to be identified at an earlier stage and enable us to provide treatment. CBNAAT being a sensitive test picked up more cases than histopathology, culture, AFB stain. Hence CBNAAT should be widely used for early detection of female genital tuberculosis.

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