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Original Research Article

A study on prevalence of endometrial tuberculosis in unexplained infertility using cartridge-based nucleic acid amplification test

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ABSTRACT

Background: Infertility is clinically defined as the inability to achieve pregnancy following one year of regular, unprotected intercourse. Its prevalence exhibits considerable variation across different regions, ranging between 5% and 20%. Extensive research has identified multiple etiological factors contributing to female infertility, including ovulatory dysfunction, infections of the genital tract, tubal obstruction, uterine abnormalities, endometriosis, endocrine disorders, and pelvic inflammatory diseases.
Methods: The study was conducted in the Department of Obstetrics and Gynaecology at RNT Medical College and Allied Hospitals, Udaipur from January 2024 to December 2024, in collaboration with the Department of Microbiology.
Result: Study finding shows that cartridge-based nucleic acid amplification test (CBNAAT) performed on endometrial samples. CBNAAT positivity was observed in 2 out of 70 women (2.86%), while 97.14% tested negative. The detected prevalence aligns closely with global estimates of genital tuberculosis in infertility, reinforcing the value of CBNAAT as a sensitive diagnostic tool in detecting paucibacillary forms of endometrial tuberculosis that might otherwise go undiagnosed through conventional methods.
Conclusion: Study concludes a low prevalence, underscoring that genital tuberculosis may not be a frequent cause in cases labelled as unexplained infertility. While CBNAAT demonstrated high specificity (approaching 100%), its sensitivity remains low (around 22–25%), indicating that although a positive result strongly confirms disease, a negative result does not reliably exclude it.

Keywords: Unexplained infertility, CBNAAT

INTRODUCTION

Infertility is clinically defined as the failure to conceive after one year of consistent, unprotected sexual intercourse.[1] Its global prevalence varies widely, affecting approximately 5–20% of couples across different regions.[2] Numerous studies have identified diverse causes of female infertility, such as ovulatory disorders, genital tract infections, tubal blockage, uterine pathologies, endometriosis, hormonal imbalances, and pelvic inflammatory disease.[3] Nevertheless, despite thorough diagnostic assessment, a proportion of infertility cases remain without an identifiable cause, a condition referred to as unexplained infertility. This highlights the need to investigate subtle or less apparent factors that may interfere with conception.[4] While female-related factors play a significant role in infertility, male factors contribute to nearly 40–50% of cases, either independently or in conjunction with female causes. In men, genital tuberculosis may involve the epididymis, prostate, seminal vesicles, or testes, resulting in reproductive tract obstruction, compromised spermatogenesis, and azoospermia. Due to its slow and often silent progression, male genital tuberculosis frequently remains undiagnosed, particularly in individuals with normal semen parameters or unexplained infertility.

Genital tuberculosis (GTB), an extrapulmonary manifestation of infection caused by *Mycobacterium tuberculosis*, is recognized as an important yet underdiagnosed cause of infertility, especially in low- and middle-income countries.[5] Globally, it is estimated that 5–10% of infertile women are affected by GTB, with prevalence rates below 1% in developed nations and as high as 13% in developing regions. In India, GTB has been reported in approximately 3% of infertile women, with prevalence increasing to nearly 41% among those diagnosed with tubal factor infertility.[6] Most affected women fall within the reproductive age group of 20–40 years, underscoring the significant reproductive consequences of the disease.[7]

Earlier data from the Indian Council of Medical Research suggested a rising trend in female genital tuberculosis (FGTB), increasing from 19% in 2011 to 30% in 2015, particularly among women evaluated for infertility. More recent regional data offer a revised perspective; a 2024 study from a tertiary care center in Faridabad, Haryana, reported microbiologically confirmed FGTB in 2.73% of infertile women, predominantly in those aged 21–35 years. These findings emphasize the importance of considering GTB in cases of unexplained infertility and recurrent in-vitro fertilization failure.

Diagnosing genital tuberculosis remains challenging due to its largely asymptomatic or latent nature. Consequently, accurate identification requires a high degree of clinical suspicion and extensive diagnostic workup.[8] Traditional diagnostic methods include chest radiography, tuberculin skin testing, hysterosalpingography for tubal abnormalities, histopathological examination using acid-fast staining, and culture of endometrial tissue. However, these approaches demonstrate inconsistent sensitivity and specificity and are often inadequate for detecting paucibacillary forms of GTB, particularly endometrial tuberculosis (ETB).[9]

The female genital tract sites most frequently affected by tuberculosis, in ascending order, include the vagina (1%), uterine myometrium (2.5%), cervix (5–15%), ovaries (20–30%), endometrium, and fallopian tubes (95–100%).[10] Given this distribution, endometrial involvement is a major contributor to infertility, menstrual disturbances, chronic pelvic inflammatory disease, and dyspareunia.[11] Endometrial tuberculosis, the most common presentation of GTB, accounts for approximately 27% of extrapulmonary tuberculosis cases worldwide, with reported prevalence ranging from 14% to 41%. Epidemiological data indicate a marked global increase in incidence, rising from 2.2 crore to 186 crore cases between 1995 and 2005. Similar trends have been observed in India, where the prevalence of genital tuberculosis increased from 19% in 2011 to 30% in 2015.[12]

The primary diagnostic difficulty in endometrial tuberculosis arises from its paucibacillary nature, resulting in low bacterial load and reduced detection rates with conventional techniques.[13] Smear microscopy and culture methods, although routinely employed, have limited sensitivity, particularly in early or latent disease.[14] This underscores the need for rapid, highly sensitive, and specific diagnostic tools. Molecular diagnostic techniques, such as real-time polymerase chain reaction (PCR), have emerged as promising alternatives. Real-time quantitative micro-PCR platforms allow for the detection of *Mycobacterium tuberculosis* DNA from endometrial biopsy specimens and can simultaneously identify rifampicin resistance, with results available within approximately one hour.[15]

PCR-based assays are increasingly favored due to their superior diagnostic accuracy compared to traditional methods.[16] In recent years, the GeneXpert system, which employs the cartridge-based nucleic acid amplification test (CBNAAT), has gained widespread acceptance as a rapid, automated diagnostic tool. CBNAAT enables direct detection of *Mycobacterium tuberculosis* DNA from clinical samples while concurrently assessing rifampicin resistance, delivering results within two hours. This technology has demonstrated high reliability in pulmonary tuberculosis and is now being actively evaluated for extrapulmonary forms, including endometrial tuberculosis.[17]

Advanced molecular diagnostic approaches, particularly PCR and CBNAAT, offer significant advantages in overcoming the limitations of conventional diagnostic methods. GeneXpert has shown high sensitivity and specificity, enabling early diagnosis and timely initiation of treatment. While its utility in pulmonary tuberculosis is well established, further research is required to validate and optimize the use of CBNAAT in extrapulmonary tuberculosis, particularly endometrial tuberculosis.

Aim and objectives

The aim of this study was to investigate the prevalence of endometrial tuberculosis among women presenting with unexplained infertility and to evaluate the diagnostic utility of the CBNAAT in the detection of endometrial tuberculosis.

The objectives were to determine the prevalence rate of endometrial tuberculosis in women with unexplained infertility and to evaluate the role of CBNAAT as a rapid and reliable diagnostic tool in comparison to conventional diagnostic methods for endometrial tuberculosis.

METHODS

Study permission

The necessary approvals were obtained from the Institutional Ethical Committee and the Research Review Board of RNT Medical College and Allied Hospitals, Udaipur, prior initiating the study.

Place of study

The study was conducted in the Department of Obstetrics and Gynaecology at RNT Medical College and Allied Hospitals, Udaipur from January 2024 to December 2024, in collaboration with the Department of Microbiology.

Study type

Hospital-based descriptive cross-sectional study was employed.

Study design

Observational study was employed.

Study population

Women presenting with unexplained primary or secondary infertility in the Department of Obstetrics and Gynaecology, fulfilling the eligibility criteria.

Sample size

The sample size was calculated based on the prevalence of genital tuberculosis in unexplained infertility, reported to be 4% in previous studies, using the formula given.

$$N = Z^2 \times (PQ/L^2)$$

The calculated sample size was 60 participants. Accounting for a 10% non-response rate, the final sample size was rounded to 70 participants.

Sampling technique

Consecutive sampling of eligible participants meeting the inclusion criteria during the study period.

Inclusion criteria

Inclusion criteria included women aged 20–40 years presenting with unexplained primary or secondary infertility with no identifiable cause after routine investigations.

Exclusion criteria

Exclusion criteria included male factor infertility confirmed by semen analysis, women with identifiable causes of infertility such as polycystic ovarian syndrome, endocrine disorders, anatomical factors (e.g., fibroids, polyps, septate uterus) confirmed by ultrasonography, magnetic resonance imaging (MRI), or diagnostic hysterolaparoscopy, patients with a previous history of tuberculosis or anti-tubercular therapy, women with active pelvic infections or chronic illnesses such as diabetes, HIV, or autoimmune disorders and women unwilling to provide consent for participation.

Statistical analysis

The data were entered into Microsoft Excel and analyzed using statistical package for the social sciences (SPSS) version 23.

RESULTS

The present study was conducted as a hospital-based descriptive cross-sectional study in the Department of Obstetrics and Gynaecology, RNT Medical College and Allied Hospitals, Udaipur, from January 2024 to December 2024. A total of 70 women aged 20 to 40 years, presenting with unexplained primary or secondary infertility and meeting the inclusion criteria, were enrolled consecutively after ruling out male infertility.

The biopsy samples were collected using a manual vacuum aspiration (MVA) syringe and sent in a vial for normal saline for analysis using CBNAAT to detect the presence of *Mycobacterium tuberculosis* DNA and rifampicin resistance. Relevant demographic, clinical, hormonal, and radiological data were recorded. The data were compiled and analysed using appropriate statistical methods to explore the relationship between clinical findings and CBNAAT positivity, and to evaluate the role of molecular diagnostics in the workup of infertility.

Table 1 shows the mean age of the participants was 30.34±6.23 years. This indicates that a significant proportion of women seeking evaluation for unexplained infertility in this study were in their early to mid-thirties, corresponding with the critical reproductive age range.

Table 1: Distribution of subjects according to age.

Age group (years)	Number of subjects	Percentage (%)
20–24	16	22.86
25–29	16	22.86
30–34	18	25.71
35–40	20	28.57
Total	70	100.00
Mean±SD	30.34±06.23	

Table 2 details the mean body mass index (BMI) was 23.88±4.94 kg/m². These findings highlight that approximately 44.29% of women had BMI levels above the normal range, emphasizing the relevance of weight-related evaluation in infertility assessment.

Distribution according to marital duration (years)

Data summarizes the marital duration of the study participants. The highest proportion (41.43%) had been married for 6–10 years, followed by 31.43% with ≤5 years of marital life, and 27.14% with >10 years. The mean marital duration was 7.67±3.94 years. These figures indicate that most women had a sufficiently long duration

of attempted conception without success, reinforcing their classification as infertile under standard definitions.

Table 2: Distribution according to BMI (kg/m²).

BMI category	Number of subjects	Percentage (%)
<18.5 (underweight)	11	15.71
18.5–24.9 (normal)	28	40.00
25–29.9 (overweight)	20	28.58
≥30 (obese)	11	15.71
Total	70	100.00
Mean±SD	23.88±04.94	

Distribution according to socioeconomic status

The participants based on socioeconomic status using the modified Kuppuswamy scale. A substantial portion belonged to the upper-lower (35.71%) and lower-middle (28.57%) classes, whereas only 4.29% came from the upper class. The observed distribution was statistically significant (χ^2=18.9, df=4, p<0.001), indicating a skew toward middle and lower socioeconomic strata. This finding may imply that women from lower economic backgrounds are more likely to present with or be diagnosed with unexplained infertility. Limited access to comprehensive fertility investigations and delayed referrals due to financial constraints may be contributing factors. Conversely, the representation from higher socioeconomic groups was relatively low, possibly due to preference for private or advanced fertility care centers,

As seen in Table 3, 60% of the women had no identifiable medical comorbidity, while 40% had at least one condition. The most common was hypothyroidism (14.29%), followed by obesity (11.43%), hypertension (8.57%), and diabetes mellitus (5.71%). The distribution of comorbidities was also statistically significant (χ^2=29.9, df=4, p<0.001), suggesting that these conditions were non-randomly distributed in the study population.

Hypothyroidism and obesity, known to affect ovulatory cycles and endometrial receptivity, may play a role in subtle reproductive dysfunction, even if they do not manifest overtly on ultrasonographic or hormonal screening. Nevertheless, the predominance of patients without comorbidities supports the classification of infertility as 'unexplained' in a majority of the cases.

Table 4 illustrates the distribution of subjects according to the type of infertility. Primary infertility was observed in 71.40% of participants, while 28.60% were categorized as having secondary infertility. The difference in proportions was statistically significant (χ^2=12.9, df=1, p<0.001). The predominance of primary infertility in this cohort is expected, as most women were nulligravida and nulliparous, with minimal prior conceptions or reproductive events, as demonstrated in earlier tables.

Table 5 summarizes the obstetric profile of the 20 women with secondary infertility. While a majority had a history of live births (75%), 25% reported no live births despite prior pregnancies, and 35% had experienced one abortion. Notably, 25% remained nulliparous, highlighting reproductive challenges despite previous conceptions. These findings underscore the diverse reproductive backgrounds within the secondary infertility group, distinguishing them from the predominantly nulligravida primary infertility cohort.

Table 3: Distribution according to medical comorbidities.

Comorbidity	Number of subjects	Percentage (%)
Hypothyroidism	10	14.29
Obesity (BMI >30)	8	11.43
Hypertension	6	8.57
Diabetes mellitus	4	5.71
No comorbidity	42	60.00
Total	70	100.00
χ^2 goodness of fit		
χ^2	29.9	
Df	4	
P value	<0.001	

Table 4: Distribution according to type of infertility.

Type of infertility	Number of subjects	Percentage (%)
Primary	50	71.40
Secondary	20	28.60
Total	70	100.00
χ^2 goodness of fit		
χ^2	12.9	
df	1	
P value	<0.001	

Distribution according to per speculum examination findings

The findings on per speculum examination. Normal findings were observed in 75.70% of participants. Cervical erosion and abnormal discharge were noted in 10.00% and 14.30%, respectively. The difference in examination findings was statistically significant (χ^2=56.8, df=2, p<0.001). While the majority had no observable cervical pathology, the presence of discharge or erosion in a subset warrants further exploration, particularly in the context of infectious or inflammatory causes of infertility.

Table 6 results underscore that although a subset of women may present with identifiable pelvic abnormalities on sonography, a significant proportion (nearly three-quarters) do not show overt ultrasonographic pathology. This supports the categorization of many cases under

'unexplained infertility,' where structural evaluation by sonography fails to reveal a clear etiology.

Table 5: Reproductive history among subjects with secondary infertility (n=20).

Parameter	Category	Number of subjects	Percentage (%)
Abortions	0	13	65.00
	1	07	35.00
	≥2	00	00.00
Parity (para)	0	05	25.00
	1	06	30.00
	2	05	25.00
	≥3	04	20.00
Live births	0	05	25.00
	1	08	40.00
	≥2	07	35.00

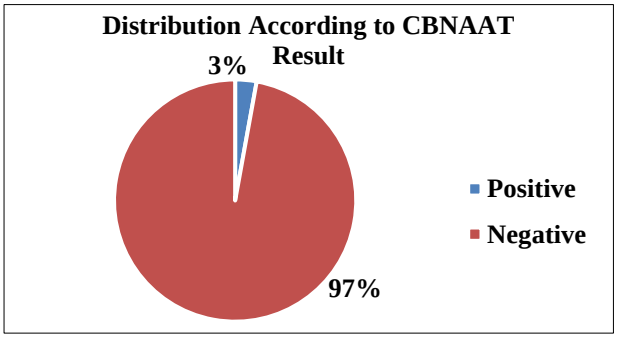

Figure 1: Distribution according to CBNAAT result.

Table 7 finding suggest that thyroid dysfunction, hyperprolactinemia, or diminished ovarian reserve were not major contributing factors to infertility in this cohort.

Figure 1 reports the findings of the CBNAAT performed on endometrial samples. CBNAAT positivity was observed in 2 out of 70 women (2.86%), while the remaining 97.14% tested negative. The result was statistically significant (χ^2=62.2, df=1, p<0.001). The detected prevalence aligns closely with global estimates of genital tuberculosis in infertility, reinforcing the value of CBNAAT as a sensitive diagnostic tool in detecting paucibacillary forms of endometrial tuberculosis that might otherwise go undiagnosed through conventional methods.

Table 6: Distribution according to USG findings.

USG finding	Number of subjects	Percentage (%)
Normal	51	72.90
Ovarian cyst	05	07.14
PCOS	04	05.71
PID	03	04.29
Endometrial fluid	04	05.71
Cervicitis	03	04.29
Total	70	100.00
χ^2 goodness of fit		
χ^2	14.6	
df	1	
P value	<0.001	

Table 7: Distribution according to hormonal parameters (TSH, Prolactin, AMH).

Parameter	Range	Number of subjects	Percentage (%)	Mean±SD
TSH (µIU/ml)	<0.4	00	00.00	2.75±0.73
	0.4–4.0 (normal)	67	95.71	
	>4.0 to <10.0	03	04.29	
Prolactin (ng/ml)	<5.0	04	05.71	11.72±4.00
	5-25 (normal)	66	94.29	
	>25.0 to <100.0	00	00.00	
AMH (ng/ml)	1.0-4.5 (normal)	50	71.43	3.76±1.20
	>4.5	20	28.57	

DISCUSSION

This hospital-based descriptive cross-sectional study was conducted to assess the prevalence of endometrial tuberculosis in women presenting with unexplained infertility, utilizing CBNAAT as the diagnostic modality. The study was carried out in the Department of Obstetrics and Gynaecology at RNT Medical College and Allied Hospitals, Udaipur, over a period of 12 months from January 2024 to December 2024. A total of 70 women meeting the inclusion criteria were enrolled consecutively. Each participant underwent detailed clinical assessment and premenstrual endometrial biopsy, with the collected samples analysed using CBNAAT to detect *Mycobacterium tuberculosis* DNA and rifampicin resistance. The results were interpreted in the context of existing literature, comparing the observed prevalence and diagnostic yield with findings from previous studies to evaluate the clinical utility of CBNAAT in diagnosing endometrial tuberculosis.

In the present study (Table 1), the majority of women with unexplained infertility were in the 35–40 years age group (28.57%), followed by the 30–34 group (25.71%), with a mean age of 30.34±6.23 years. These findings align with those of Sri et al, who reported a predominant age range of 21–30 years among infertile women with suspected FGTB,

and Tiwari et al, who observed CBNAAT positivity mainly in women aged 30–39.[18,19] Despite these variations, the clustering of cases around the early thirties in our study is consistent with the critical reproductive age range reported in most literature, reflecting the peak fertility-seeking period during which women are more likely to undergo investigation for unexplained infertility and be diagnosed with conditions like endometrial tuberculosis.

In the present study (Table 2), the mean BMI was 23.88±4.94 kg/m², finding consistent with Sharma et al, who observed a strong association between higher BMI and menstrual irregularities in women with suspected genital TB.[20] Similarly, Sri et al noted that a large subset of infertile women in their cohort were either overweight or obese, although they did not establish a causal relationship with TB positivity.[18] Overall, the trend of elevated BMI in a significant proportion of women with unexplained infertility across studies, including the present one, supports its consideration as a metabolic cofactor, even if not directly linked to endometrial tuberculosis. Variation across studies likely stems from regional lifestyle, dietary habits, and urban versus rural sampling differences.

Marital duration

In the present study, the majority of women had a marital duration of 6–10 years (41.43%), followed by ≤5 years (31.43%) and >10 years (27.14%), with a mean marital duration of 7.67±3.94 years. This indicates that most participants had been attempting conception for several years, fitting the clinical definition of infertility. These findings are consistent with Sri et al, who reported that 95% of suspected genital TB cases had primary infertility and had been married for over 5 years without conception.[18] The consistent association between longer marital duration and suspicion or diagnosis of FGTB across multiple studies, including ours, suggests that undiagnosed genital TB may be a contributing factor in prolonged unexplained infertility, justifying its inclusion in early diagnostic screening algorithms, especially in TB-endemic areas.

Socioeconomic status

In the present study, the majority of women belonged to the upper-lower (35.71%) and lower-middle (28.57%) socioeconomic classes, while only 4.29% were from the upper class. These findings are consistent with, who reported that most patients with endometrial TB belonged to lower-income households, attributing this to poor nutritional status, delayed medical consultation, and lack of awareness.[18] Sharma et al and Tiwari et al also found a disproportionately high number of FGTB cases among women from economically disadvantaged back-grounds.[20,19] The present findings and supporting literature collectively suggest that lower socioeconomic status is a major risk factor not only for delayed infertility evaluation but also for undiagnosed FGTB, highlighting the need for targeted screening and subsidized molecular diagnostics in vulnerable populations.

In the present study (Table 3), 60% of participants had no identifiable medical comorbidity, while among the 40% with comorbidities, hypothyroidism (14.29%) was the most prevalent, followed by obesity (11.43%), hypertension (8.57%), and diabetes mellitus (5.71%); this distribution was statistically significant (χ^2=29.9, p<0.001). These findings are in line with Sharma et al, who reported a significant association between hypothyroidism and infertility in women suspected of having FGTB, highlighting thyroid dysfunction as a common coexisting endocrine disorder.[20]

Our study supports the notion that while a majority of women with unexplained infertility may appear medically healthy, subtle or subclinical conditions like hypothyroidism and obesity can coexist with genital TB, complicating diagnosis and reinforcing the need for inclusive diagnostic protocols that assess both endocrine and infectious etiologies.

In the present study (Table 4), primary infertility was observed in 71.40% of participants, while 28.60% had secondary infertility; this difference was statistically significant (χ^2=12.9, p<0.001), indicating a predominance of primary infertility among women with unexplained infertility. These findings are strongly supported by Sri et al, who reported that 95% of women diagnosed with FGTB had primary infertility, suggesting a strong association between TB and initial failure to conceive.[18] Yadav and Kumar also found a higher prevalence of primary infertility among women diagnosed with endometrial TB, highlighting that TB often affects women before they have achieved any pregnancy.[21] The findings from our study and multiple supporting studies clearly establish that FGTB tends to manifest more often in women who have never conceived, likely due to early endometrial involvement impairing implantation or endometrial receptivity, making primary infertility a significant clinical clue in suspecting genital tuberculosis.

In the present study (Table 5), among the 20 women with secondary infertility, 75% had a history of live births, 25% were nulliparous, and 35% had experienced at least one abortion; parity was most commonly P1 (30%) and P2 (25%). These findings reflect a diverse obstetric background among women with secondary infertility. Comparable patterns were observed in Yadav and Kumar, who reported that a subset of women diagnosed with FGTB had previously conceived but later developed infertility due to tubal or endometrial scarring.[21]

Our study, suggests that latent or subclinical TB can emerge later in reproductive life, impairing future conception particularly through subtle endometrial damage highlighting the need for molecular screening like CBNAAT even in women with prior successful pregnancies.

Per speculum examination

In the present study, per speculum examination revealed normal findings in 75.70% of participants, while cervical erosion and abnormal discharge were noted in 10.00% and 14.30% of women, respectively; the distribution was statistically significant (χ^2=56.8, p<0.001). These results are consistent with Sharma et al, who reported that while most FGTB cases had unremarkable pelvic exams, a subset showed signs of cervical inflammation or abnormal discharge, which were later linked to TB positivity.[20] The findings in our study align with the broader consensus that while most cases of endometrial TB may not show specific speculum findings, the presence of cervical erosion or unexplained discharge especially in the absence of other etiologies should raise suspicion for FGTB and warrant further molecular evaluation like CBNAAT.

In the present study (Table 6), ultrasonography (USG) revealed normal findings in 72.90% of participants, while abnormalities were identified in 27.10%, including ovarian cysts (7.14%), polycystic ovarian syndrome (PCOS) and endometrial fluid (each 5.71%), and findings suggestive of PID and cervicitis (each 4.29%); the distribution was statistically significant (χ^2=14.6, p<0.001). These findings are in line with Sri et al, who observed that many women with genital TB had normal pelvic USG, underscoring its limitations in detecting endometrial involvement.[18] Similarly, Sharma et al reported that while USG could reveal ovarian cysts or free fluid in some TB cases, it failed to detect subtle endometrial pathology, necessitating further testing like CBNAAT.[20] Thus, our study reinforces that although a minority of patients may present with USG abnormalities like cysts or endometrial fluid, the high proportion of normal scans supports existing literature that TB often eludes detection on imaging, and molecular diagnostics like CBNAAT are essential for confirming FGTB in unexplained infertility.

In the present study (Table 7), hormonal evaluation showed that 95.71% of participants had normal thyroid-stimulating hormone (TSH) levels (mean 2.75±0.73 µIU/ml), and 94.29% had normal serum prolactin levels (mean 11.72±4.00 ng/ml), while anti-Müllerian hormone (AMH) was within the normal range (1.0–4.5 ng/ml) in 71.43% of cases (mean 3.76±1.20 ng/ml), indicating overall preserved endocrine and ovarian function. These results align with Eftekhar et al, who reported that all women in their study had normal hormonal profiles and were TB-negative, emphasizing the importance of ruling out other causes in unexplained infertility.[22] Sri et al also found that most women with genital TB had no overt hormonal abnormalities, although subtle disruptions could occur due to endometrial pathology.[18] Our findings thus corroborate the prevailing evidence that while endocrine causes should be ruled out in infertility, normal hormonal values do not preclude the presence of endometrial tuberculosis, highlighting the value of endometrial molecular testing like CBNAAT in normoendocrine infertile women.

In the present study (Figure 1), CBNAAT testing of endometrial samples yielded a positive result in 2 out of 70 women (2.86%), while 97.14% tested negative. These findings are consistent with Kanti et al, who also reported a CBNAAT positivity rate of 2.23% among infertile women, matching the rate observed in our study.[23] Naaz et al similarly reported a 4% detection rate via GeneXpert (CBNAAT) in endometrial samples, underscoring its utility in identifying otherwise undetectable FGTB cases.[24] Chaudhary et al found a 5% positivity rate using CBNAAT, higher than our study but still indicative of FGTB's low-yield, paucibacillary nature.[25] Overall, our study supports the growing body of literature that CBNAAT, though yielding a low positivity rate, is a valuable and rapid diagnostic tool for identifying endometrial tuberculosis in women with unexplained infertility, particularly in TB-endemic regions, where even a single missed case may lead to irreversible reproductive damage.

CONCLUSION

The present study aimed to determine the prevalence of ETB in women presenting with unexplained infertility and to assess the diagnostic utility of CBNAAT. We found a low prevalence, underscoring that genital tuberculosis may not be a frequent cause in cases labelled as unexplained infertility. While CBNAAT demonstrated high specificity (approaching 100%), its sensitivity remains low (around 22–25%), indicating that although a positive result strongly confirms disease, a negative result does not reliably exclude it. Accordingly, routine application of CBNAAT in all unexplained infertility cases may have limited value, particularly in low-prevalence settings. However, its strength lies in a targeted approach—using CBNAAT selectively for women with high clinical suspicion (e.g., menstrual irregularities, chronic pelvic pain, prior TB exposure), where its high specificity can efficiently confirm disease with minimal false positives. This judicious use, guided by clinical judgment, optimizes diagnostic efficiency and resource utilization in constrained settings. Therefore, CBNAAT should complement not replace clinical assessment, ensuring that its use enhances decision-making without over-reliance. Future large-scale, multicentric studies are warranted to refine screening thresholds, explore combinations of diagnostic modalities (e.g., histopathology, culture, CBNAAT), and develop cost-effective protocols tailored to varied TB prevalence environments.

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