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Role Of Empirical Therapy In Infertility In A Private Health Care

Dr Kanak Lata, Dr Geeta Sinha Manki
M.S Obs N Gynae, Ex Scmo Bsmch, Wb, Hod Obg At Ccl, Ramgarh)
Ex Cs Ramgarh, Ex Consultant At Sadar Hospital, Ramgarh, Consultant At Geeta Ivf Centre, Ramgarh)

Abstract:
Background*:*
Infertility is a social stigma in our society. Whatever is the reason a female is blamed in our society, and bringing joy in someons life is a gods gift especially to the female.In this study we have shown the role of empirical theray of anti TB drug in primary and secondary infertility in females.
Materials and Methods*: In this prospective randomized controlled study between the two groups Group A and Group B each containg approximately 250 females. Group A receiving Anti Tubercular drug on the basis of ESR >20mm in 1st hr , Gold TB positive . Group B not receiving any Anti TB Drug. The study was conducted over a period of 6 year from jan 2019 to dec 2024 at Geeta IVF centre, Ramgarh,Jharkhand.*
Results*: We found that 95% cases in Group A receiving Anti TB drug conceived spontaneously over a period of first 6month the treatment was prolonged to 9month, however in Group B not receiving Anti TB drug the conception rate was very low approximately 3-4%. Those positive for Gold TB and raised ESR were chosen for Anti TB drug regimen.*
Keyword- *Gold TB,Anti TB drugs, Primary infertility,ESR, Infertility,IVF,conception ,spontaneous.*

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I. Introduction

Female genital tuberculosis (FGTB) is an important variety of extrapulmonary tuberculosis (TB) causing significant morbidity in women such as menstrual dysfunction, infertility, ectopic pregnancy, and tubo-ovarian mass.[1,2,3,4] The prevalence of FGTB in infertile women ranges from 7% to 15% in developing countries rising to 26% in tertiary referral hospitals and up to 48% in tubal factor infertility[3,4,5] The infection spreads to genital organs normally by hematogenous route with the frequency of involvement of fallopian tubes (90%), endometrium (50–80%), ovaries (20–30%),cervix (5–10%), and rarely vulva and vagina.[1] FGTB is an important cause of intrauterine adhesions (Asherman's syndrome), pelvic adhesions, and perihepatic adhesions (Fitz–Hugh–Curtis syndrome).[6,7] .

II. Material And Methods

This prospective comparative study was carried out on a group of 500 patients in GeetaIVF Centre, Ramgarh, Jharkhand over a period of 6 years from jan 2019 to de 2024.

Study Design: Prospective open label observational study

Study Location: Geeta IVF VCentre, Ramgarh ,Jharkhand.

Study Duration: Jan 2019 to Dec 2024.

Sample size: 500 patients.

Sample size calculation: The sample size was estimated on the basis of a single proportion design. The target population from which we randomly selected our sample was considered 30,000. We assumed that the confidence interval of 10% and confidencelevel of 95%. The sample size actually obtained for this study was 250 patients for each group. We planned to include 250 patients (Group A, Group B- Cases of 250 patients for each group) with 4% drop out rate.

Subjects & selection method: The study population was drawn from patients reporting at Geeta IVF center with h/o primary infertility.

Group A(N=250 patients) -On Anti TB drugs for 9months.
Group B (N=250 patients)- Non Anti TB drugs.

Inclusion criteria:
1. Primary infertility.
2. Raised ESR>20mm in first hour.
3. Positive GOLD TB test
4. Aged ≥ 18 years,
5.Married women
6. Normal LFT .
7.Tolerant to Anti TB drugs.

Exclusion criteria:
1. Gold Tb negative.
2. Abnormal Liver function Test.
3. Intolerant to TB drugs
4. Normal ESR.
5. Age <18years.
6. Unmarried women

Procedure methodology

After written informed consent was obtained, a well-designed questionnaire was used to collect the data of the recruited patients retrospectively. The questionnaire included socio-demographic characteristics such as age ,marital status , years of infertility, previous treatment regimen.

The prescribed Drug were given as follows:
Group A-On Anti Tb Drugs for 9month.
Group B -Control Group B ,not receiving any Anti TB drugs .

All the cases in Group A received Anti TB drug after fulfilling the inclusion criteria, like raised ESR>20 mm in first hour, Gold TB positive ,primary infertility not responding to conventional drugs. They took complete course of 9months with other drugs like folvite , liver protective drugs to reduce the side effects of Anti Tb drugs.

The patients on Group B did not receive the Anti Tb drugs ,they took folvite, ovulatory enhancer drugs for 9months.
All patients were followed for 9months .

Statistical analysis :

Data was analyzed using SPSS version 20 (SPSS Inc., Chicago, IL). Student's *t*-test was used to ascertain the significance of differences between mean values of two continuous variables and confirmed by nonparametric Mann-Whitney test.

III. Result

All patients 500 after 9 months were compared. It was surprising fact that most of the patients in Group a conceived spontaneously in first 8weeks of ATT drugs as they were followed every 30 days for conception.

Table 1 shows comparitive study on spontaneous conception, abortion rates , Defaulters , Effect on continuing Anti TB drugs during pregnancy , effect on babies after birth.

Observation	Group A	Group B	%
1.Spontaneous conception rate	96 %	3 %	
2. Defaulters	4%	Nil	
3. Abortion in first TRM	1%	1 %	
4.Adverse Effect on pregnancy	nil	nil	
5. Adverse Effect on liver function test	3-4%	nil	
6.NICU admission	Nil	1%	
7.Baby growth after birth	normal	Normal	
8.Adverse effect on fetus in intrauterine	Nil	Nil	
9.Need of continuance of Anti Tb drugs to new born baby	Only in extreme drug resistance cases	Nil	

IV. Discussion

FGTB is a common disease in developing countries causing significant morbidity, especially infertility[1-5]. Being paucibacillary disease, its diagnosis, especially in the early stage, is a diagnostic challenge. Combinations of tests are performed to reach a diagnosis.[16,17] These include endometrial sampling for AFB on microscopy or culture, PCR for M. tuberculosis, histopathological evidence of epithelioid granuloma, laparoscopic, and/or hysteroscopic evidence of FGTB.[8,16] Ultrasound, CT scan, MRI, and PET scan are more useful for FGTB with tuboovarian mass, especially when the differential diagnosis is ovarian cancer as FGTB is known to masquerade as ovarian cancer.[1,10,11,19]Some authors have made an algorithm by combining various tests for early diagnosis of FGTB[17]

Direct ovarian involvement in FGTB occurs less commonly (20–30%). However, even in the absence of direct ovarian involvement, FGTB affects ovarian function, especially ovarian reserve as observed by other authors in their study.[12,14] Adequate follicular development in response to gonadotrophins is dependent on the ovarian reserve at that period of time. Various tests of ovarian reserve such as AMH, FSH, and AFC have become a part of the routine diagnostic procedure for infertility patients. Recent studies have shown decreased ovarian reserve in FGTB patients.[12,14] Poor ovarian blood flow has also been observed in infertile women with FGTB undergoing assisted reproduction.[20]Although many studies have observed the effect of FGTB on ovarian function, no study in our knowledge has observed the effect of ATT on ovarian function in FGTB. In the present study, performed in FGTB patients without obvious ovarian involvement (cases with tuboovarian mass were excluded) diagnosed by endometrial aspiration studies showing evidence of AFB on culture or microscopy, histopathological evidence of epithelioid granuloma, positive PCR along with findings on laparoscopy and/or hysteroscopy, and ovarian function was assessed at enrolment. The women were then given 6 months course of ATT. Ovarian function was then reassessed after completion of ATT in all women (except two women who conceived during treatment). We observed a significant increase in AMH levels with ATT and a nonsignificant increase in FSH levels with ATT. The rise in FSH in FGTB could be due to the antigonadotropic effect of M. tuberculosis as has been observed by Kumar and Rattan in their study[15] AMH has been observed to be a superior marker for predicting both oocyte number and quality.[21,22] However, there is no literature on AMH levels in FGTB patients. In the present study, there was an increase in AMH levels, nonsignificant increase in FSH levels, and significant increase in AFC using ATT. M. tuberculosis has an antigonadotropic effect. After ATT, toxins disappeared improving gonadotropic levels.

V. Conclusion

Empirical therapy .in infertility is really very effective. We have minimal side effect of few anti TB crugs like rifampicin that also can be controlled by taking liver protective drugs and healthy food habits. We have to strictly follow the patients so that they continue this regimen for the given time period. Now CDC has provided new regimen of only 6 month anti TB drugs which is conventional to the patients.

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