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**Original Research Article**

# Comparative study of maternal and fetal outcome of tuberculosis in pregnancy in tertiary care centre

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## ABSTRACT

**Background:** Tuberculosis remains a major public health challenge worldwide. TB among pregnant women can adversely affect health of the mother and fetus. Present study is aimed to determine the prevalence of the tuberculosis and to evaluate the risks of adverse pregnancy outcome in maternal tuberculosis.
**Methods:** This was a prospective observational study done in tertiary care center over a period of 1.5 year from January 2019 to July 2021. Institute ethical committee approval was obtained. Pregnant women in the age group 18-42 years diagnosed with tuberculosis in antenatal period were included in our study for evaluating maternal and fetal outcomes. Data collected was entered in Microsoft excel sheet and analyzed. The qualitative and quantitative variables were categorized and expressed in terms of percentages or mean and standard deviations. The difference between the proportions was analyzed using chi- square or Fisher exact test. Student t test was used to test the difference between the means.
**Results:** The prevalence rate of tuberculosis in antenatal women at our institute during study period is 2.019/1000 per pregnant women. Our study shows the higher risk of preterm labour, anaemia, ARDS, retroviral disease, threatened abortion and intrauterine growth restriction with tuberculosis in pregnancy. Tuberculosis has adverse effect on maternal and fetal outcome.
**Conclusions:** Preconceptional counselling and early antenatal visits are important opportunities to screen and diagnose TB early in its coarse and ensure adequate treatment as per national programme. This will optimize the maternal and perinatal outcome.

**Keywords:** Tuberculosis, Maternal outcome, Foetal outcome

## INTRODUCTION

Tuberculosis (TB) remains a major public health challenge worldwide.[1] Reproductive age group (15-49 years) women bear a massive burden of TB in India and globally.[2] TB among pregnant women can adversely affect health of the mother, fetus, neonate and their children with wide spectrum of short-term and long-term implications.[3] TB in pregnancy could have serial and sequential effect such as repeated reproductive failure, fetal ill-health, preterm delivery, and TB of the newborns and infants leading to high maternal and perinatal morbidity and mortality.[4] There is increasing evidence that undernutrition in patients with active TB is associated with a two to fournfold increase in mortality, with a five-fold risk of drug-induced hepatotoxicity, and patients are unable to regain a normal weight, despite effective treatment in the setting of poverty and food

insecurity.[5] The prevalence of TB among pregnant women is largely unknown. The incidence of tuberculosis in pregnancy is not readily available in many countries due to a lot of confounding factors. However, it is expected that the incidence of tuberculosis among pregnant women would be as high as in the general population, with possibly higher incidence in developing countries. Two independent estimates suggest that the burden of active TB cases in pregnant women in India is substantial. The proportion of tuberculosis varies with respect to geographical, social, ethical and economical parameter.[16] Many studies show there is significant increase in risk of active tuberculosis infection seen in both antenatal and postnatal women in high incidence countries like India although many reports are conflicting too.[17] Indirect maternal death now account for 28% of total maternal death out of these 15-35% deaths due to tuberculosis.[4] Several studies shows that tuberculosis in pregnancy has been associated with poor obstetrical, fetal and perinatal outcome. But early diagnosis of tuberculosis still remains the biggest obstacle in the management of the disease.[18] In recent post mortem analysis of maternal deaths highlights that infection, including TB, is an important contributor to maternal death in India.[19] However, studies comparing maternal and fetal outcome in antenatal women with tuberculosis is scanty therefore in present study is aimed to determine the prevalence of the tuberculosis and to evaluate the risks of adverse pregnancy outcome in maternal tuberculosis. We outline and identify the demographic and clinical characteristics of tuberculosis and we compared the course of pregnancy and labour and perinatal outcome among antenatal women with tuberculosis and matched control women.

### *Objectives*

The objectives of the study were to determine the prevalence of tuberculosis in antenatal women, to assess the feto maternal outcome of antenatal women infected with tuberculosis, to assess influence of tuberculosis on the pregnancy, to assess the epidemiological aspects of tuberculosis in antenatal women infected with tuberculosis and to analyze the maternal death if any of antenatal women infected with tuberculosis.

## METHODS

This was a prospective observational study done at Grant Medical College, Mumbai over a period of 1.5 year from January 2019 to July 2021. Institute ethical committee approval was obtained. Pregnant women in the age group 18-42 years diagnosed with tuberculosis in antenatal period were included in our study for evaluating maternal and fetal outcomes. They were evaluated prospectively for the symptoms including investigation such as sputum for AFB and chest x-ray particularly for those with clinically advanced pulmonary disease, after informing and taking consent that the radiation dosage <0.01 mGy is safe in pregnancy, gene expert and further multidisciplinary work up involving microbiological and pulmonary medicine expert opinion. Data collected from individual case records included age, parity, time of diagnosis, complication in the antenatal, intra-partum and postpartum period. The mean birth weights of infant and frequency of small for gestation, neonatal depression, neonatal death, APGAR score, NICU admission and still birth were noted and perinatal outcome was seen.

### *Inclusion criteria*

All pregnant women who were diagnosed with tuberculosis in age group of 18-42 years, irrespective of period of gestation and diagnosis of tuberculosis confirmed by any biochemical, microbiological and radiological method were included in the study.

### *Exclusion criteria*

Past history of tuberculosis and adequately treated patients were excluded from the study.

### *Procedure*

All report were in accordance with the ethical guidelines of the institute's research committee. Informed consent was taken from the participants involved in this study in the language best known to them. The following outcome measures were analyzed in patients with tuberculosis: the prevalence, fetal and maternal outcome of antenatal women infected with tuberculosis, influence of tuberculosis on the pregnancy, epidemiological aspects of tuberculosis in antenatal women infected with tuberculosis, maternal death if any of antenatal women infected with Tuberculosis.

### *Statistical analysis*

After collection of relevant data, it was entered in Microsoft excel sheet and analysis was done using SPSS (statistical package of social sciences) version 20 and EpiInfo version 7.2.1. The qualitative variables were expressed in the term of percentages. The quantitative variables were both categorized and expressed in terms of percentages or in terms of mean and standard deviations. The difference between the proportions was analyzed using chi- square or Fisher exact test. Student t test was used to test the difference between the means. All analysis was 2 tailed and the significance level was set at 0.05.

## RESULTS

### *Prevalence rate of tuberculosis in antenatal patients*

In our study, 5200 study subject delivered during study period among thesestudy subject 105 were diagnosed with tuberculosis in antenatal period making prevalence rate 2.019 per 1000 pregnant women in our study. In this study 80/105 (76.19%) diagnosed with pulmonary

tuberculosis and 25/105 (23.80%) cases diagnosed with extrapulmonary tuberculosis.

***Distribution of study subject based on age***

Among the tuberculosis infected antenatal cases, 3.81% were between 18 to 20 years age, 87.82% were among 21 to 30 years and 8.57% more than 30 years of age. Among the antenatal women without tuberculosis (controls) 4.29% were 18 to 20 years age, 89.52% were 21 to 30 years and 6.19% more than 30 years of age. Mean age of antenatal women with tuberculosis was 22.63±3.42 years and for antenatal women without tuberculosis was 25.32±1.63. Majority of women were multigravida in both group.

***Distribution of subject as per socioeconomic status (classificationaccording to Prasad scale)***

Antenatal women with tuberculosis cases belong to middle and lower socioeconomic strata according to prasad scale. 62 (59.04%) of the total cases were from the middle-class families while rest of the 43 (40.95%) cases were from lower class families.

***Distribution of subjects based on registration status***

About 81.90% of antenatal women with tuberculosis and 94.76% of controls wereregistered and this difference was statistically significant (p=0.0002).

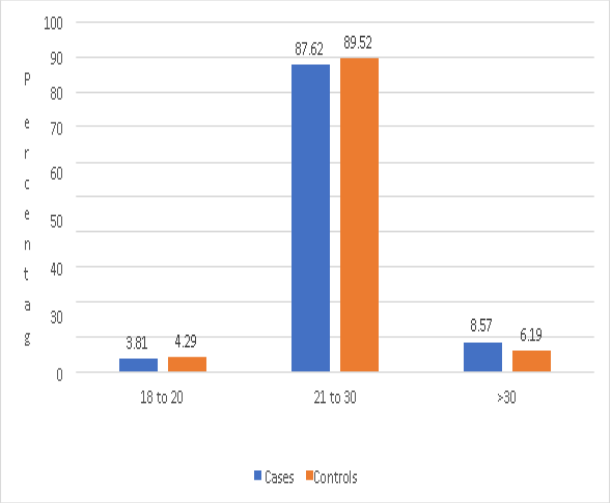


**Figure 1: Distribution of study subject based on age.**

**Table 1: distribution as per socioeconomic status cases.**

| Socioeconomic status | Antenatal women with tuberculosis (N=105) | Antenatal women without tuberculosis (N=210) |
|---|---|---|
| **Upper** | 0 | 8 |
| **Middle** | 62 | 110 |
| **Lower** | 43 | 82 |

**Table 2: Distribution of the study subjects based on the antenatal registration.**

| Registered | Antenatal women with tuberculosis (N=105) | Antenatal women without tuberculosis (N=210) | Total | P value |
|---|---|---|---|---|
| **Yes** | 86 | 199 | 285 | 0.0002 |
| **No** | 19 | 11 | 30 | |
| **Total** | 105 | 210 | 315 | |

***Distribution of subjects based on antenatal complication***

The proportion of anaemia, IUGR, threatened abortion, retroviral disease and ARDS was significantly higher among the cases of tuberculosis when compared to controls in the present study. The other maternal complications and co morbidities did not differ significantly among the two groups. Among complication anaemia most common maternal complication in both groups i.e. antenatal women infected with tuberculosis (36.19%) and antenatal women without tuberculosis (7.14%) this difference statistically significant (p<0.001). The second most common complication in cases of antenatal women with pulmonary tuberculosis was acute respiratory distress syndrome (10.48%) which less commonly seen in control group (0.48%) this difference significant (p<0.001). Intrauterine growth restriction found to be most common foetal complication in antenatal women with tuberculosis (6.67%) and as compared to antenatal women without tuberculosis group (0.95%) this difference statistically significant (p<0.0041). Retroviral disease associated with tuberculosis is more common than control group and this difference also significant. In early pregnancy the threatened abortion commonly seen with antenatal women with tuberculosis as compare to control group. This difference significant (p<0.001). Rest other complication also seen in antenatal women with tuberculosis like oligohydramnios (0.95%), abscess formation (2.86%), drugs induced hepatitis (0.95%), eclampsia (0.95%), premature rupture of membrane (5.71%), pregnancy induced hypertension (2.86%) and varicose vein (0.95%) but the value is not statistically significant.

***Distribution of subjects based on obstetric outcome***

The proportion of live foetal outcome among antenatal with tuberculosis was 76.19% and 93.33% among antenatal women without tuberculosis and this difference was significant. The proportion of stillbirth and abortion

in case group was 23.81% whereas in control 6.67%. The proportion of foetal outcome also depends upon the time of diagnosis. In present study 23 antenatal women diagnosed with tuberculosis in first trimester, one had still birth (4.34%) while 36 women diagnosed with tuberculosis in second trimester 1 neonatal death and 7 still birth were reported. In third trimester, 24 antenatal women were diagnosed with tuberculosis and of these 6 still birth, 6 neonatal deaths reported. Most of the cases i.e., women with TB, 59 cases (56.2%) had a FTND, whereas 13 cases (12.38 %) had LSCS.

**Table 3: Distribution of the study subjects based on maternal complication.**

| Maternal complications | Cases | | Controls | | P value |
|---|---|---|---|---|---|
| | N | % | N | % | |
| **Abscess** | 3 | 2.86 | 0 | 0 | 0.0641 |
| **Anaemia** | 38 | 36.19 | 15 | 7.14 | <0.001 |
| **ARDS** | 11 | 10.48 | 1 | 0.48 | <0.001 |
| **ASD** | 0 | 0 | 1 | 0.48 | 0.4788 |
| **Cholelithiasis** | 1 | 0.95 | 0 | 0 | 0.1567 |
| **COVID-19** | 1 | 0.95 | 0 | 0 | 0.1567 |
| **Drug induced hepatitis** | 1 | 0.95 | 0 | 0 | 0.1567 |
| **Eclampsia** | 1 | 0.95 | 3 | 1.43 | 0.7217 |
| **Filariasis** | 0 | 0 | 1 | 0.48 | 0.4788 |
| **GDM** | 2 | 1.90 | 3 | 1.43 | 0.7499 |
| **Hbsag** | 0 | 0 | 1 | 0.48 | 0.4788 |
| **Hyperbilirubinemia** | 0 | 0 | 1 | 0.48 | 0.4788 |
| **Hypothyroidism** | 1 | 0.95 | 0 | 0 | 0.1567 |
| **IUGR** | 7 | 6.67 | 2 | 0.95 | 0.0041 |
| **Oligohydramnios** | 5 | 4.76 | 9 | 4.29 | 0.8432 |
| **Paraplegia** | 1 | 0.95 | 0 | 0 | 0.1566 |
| **Pregnancy induced hypertension** | 3 | 2.86 | 15 | 7.14 | 0.1223 |
| **Pleural effusion** | 1 | 0.95 | 0 | 0 | 0.1567 |
| **Polyhydramnios** | 0 | 0 | 1 | 0.48 | 0.4788 |
| **PROM** | 6 | 5.71 | 6 | 2.86 | 0.2117 |
| **Retroviral disease** | 5 | 4.76 | 2 | 0.95 | 0.0034 |
| **SLE** | 0 | 0 | 1 | 0.48 | 0.4788 |
| **Threatened abortion** | 6 | 5.71 | 0 | 0 | <0.001 |
| **Thrombocytopenia** | 1 | 0.95 | 3 | 1.43 | 0.7217 |
| **Varicose veins** | 1 | 0.95 | 0 | 0 | 0.1567 |

This difference was found to be statistically significant. (p<0.00001). It was seen that the caesarean section rate was highest in control i.e., antenatal women without tuberculosis 67 cases (31.90 %) and it was 13 (12.38%) in antenatal women with tuberculosis. This difference was found to be statistically significant (p<0.00001). The percentage prevalence of PTVD was the highest among antenatal women infected with tuberculosis i.e., 28 cases (26.66%) followed closely by those with normal antenatal women i.e., 16 cases (7.61%). This difference was found to bestatistically significant (p<0.00001).

It was seen that most the cases i.e., 36 (34.29%) had baby weight in the normal range. However, a large percentage of the cases i.e. 69 (65.71%) had low birth weight and around 4.4% had very low birth weight and extremely low birth weight 1% of the cases had large for gestational age babies. It was seen that in control group 144 (68.57%) had normal birth weight range. however, 66 (34.29%) had low birth weight. this difference was statistically significant. About 18.10% of the cases needed NICU admission and 8.57% of the controls needed NICU admission and this difference was statistically significant. Low birth weight (57.89%) was the most common reason for NICU admission followed by respiratory distress syndrome (36.84%). In this study no congenital anomalous baby seen in antenatal women with tuberculosis but in control group 12 anomalous babies. The death rates among antenatal women with tuberculosis cases were 14 (13.33%) and among the controls were 3 (1.43%) and this difference was significant.

## DISCUSSION

In our study,5200 women delivered during study period among these study subject 105 that were diagnosed with tuberculosis in antenatal period making prevalence rate 2.019 per 1000 pregnant women in our study. The world health organization estimated that India accounts for about 21% of the global burden in 2018 and the estimated prevalence of TB stands at 2.3 per 1000 pregnant women, which translates to about 44,500 patients annually.[15] The prevalence of tuberculosis in pregnancy ranges 0.06% to 0.25% in low burden areas whereas in high burden areas, its 0.07 to 0.5 % with HIV negative pregnant women which exceeds to as high as 0.7 to 11% in HIV positive females.[5] In Gupta et al study and Chopra et al study prevalence of tuberculosis was 3.4 and 1.16 per 1000 women respectively.[16,36]

**Table 4: Distribution of the study subjects based on the obstetric outcome.**

| Obstetric outcome | Antenatal women with tuberculosis (N=105) | Antenatal women without tuberculosis (N=210) | Total | P value |
|---|---|---|---|---|
| Live | 80 | 196 | 276 | <0.001 |
| Dead/SB/abortion | 25 | 14 | 39 | |
| Total | 105 | 210 | 315 | |

In this study 80/105 (76.19%) diagnosed with pulmonary tuberculosis and 25/105 (23.80%) cases diagnosed with extra pulmonary tuberculosis. In this study pulmonary tuberculosis was most common. 76.19% cases were diagnosed with pulmonary tuberculosis as compare to Chopra et al study prevalence of pulmonary tuberculosis was 38%.

25/105 (23.80%) cases diagnosed with extra-pulmonary tuberculosis as compared to 62% of extra-pulmonary tuberculosis cases in study conducted by Chopra et al 66.6% by Yadav and team and 20% as reported by Jana et al.[36,17,8] Majority of the antenatal women with tuberculosis belong to 21 to 30 years of age. Mean age of antenatal women with tuberculosis was 22.63±3.42 years. Among the study group (women with tuberculosis), most common age group was 21-30 years i.e., 89 cases (87.62%). Similarly in control group 21-30 years was most common age group i.e., 181cases (89.52%). In our study average age index 22.63±3.42 years as compared to mean age of 25.7±4.22 years, 24.78±1.22 ,25.73±2.85, 28.4±5.6 and 28.7±3.9 years in study conducted by Chopra et al, Vijayageetha et al, Shrarma et al study, Tskhay et al study and Yadav et al respectively.[36,10,17,18]

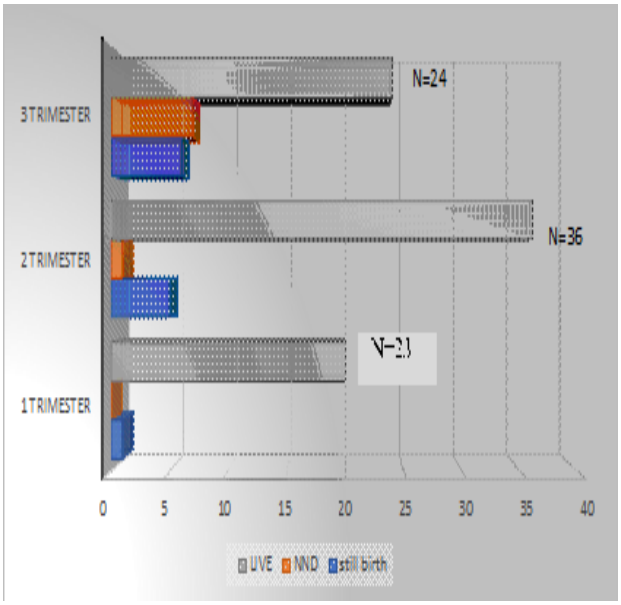


**Figure 2: Distribution of the subject based on time of diagnosis and obstetrics outcome.**

**Table 5: Distribution of the study subjects based on the mode of delivery.**

| Mode of delivery | Antenatal women with tuberculosis | Antenatal women without tuberculosis | Total | P value |
|---|---|---|---|---|
| **LSCS** | 13 | 67 | 80 | |
| **FTND** | 59 | 126 | 185 | |
| **PTVD** | 28 | 16 | 44 | 0.0001 |
| **Abortion** | 5 | 1 | 6 | |
| **Total** | 105 | 210 | 315 | |

**Table 6: Distribution of the study subjects based on the birth weight.**

| Birth weight | Antenatal women with tuberculosis (N=105) | Antenatal women without tuberculosis (N=210) | Total | P value |
|---|---|---|---|---|
| **<2.50** | 69 | 66 | 135 | |
| **≥2.50** | 36 | 144 | 180 | <0.001 |
| **Total** | 105 | 210 | 315 | |

**Table 7: Distribution of the study subjects based on NICU admissions.**

| NICU admission | Antenatalwomen with tuberculosis (N=105) | Antenatal women without tuberculosis (N=210) | Total | P value |
|---|---|---|---|---|
| **Yes** | 19 | 18 | 37 | |
| **No** | 86 | 192 | 278 | 0.0221 |
| **Total** | 105 | 210 | 315 | |

**Table 8: Distribution of the study subjects based on the maternal death.**

| Maternal deaths | Antenatalwomen with tuberculosis (N=105) | Antenatal women without tuberculosis (N=210) | Total | P value |
|---|---|---|---|---|
| **Yes** | 14 | 3 | 17 | |
| **No** | 91 | 207 | 298 | <0.001 |
| **Total** | 105 | 210 | 315 | |

In our study 29.52% of antenatal women infected with tuberculosis were referred from outside to our tertiary care centre. About 81.90% of antenatal women with tuberculosis were registered. Out of 105 antenatal women with tuberculosis, 62 (59.04%) were from middle socioeconomic strata and 43 (40.95%) from lower socioeconomic strata. In our study, 62 (80%) women were of middle socioeconomic strata and 43 (20%) antenatal women belonged to lower socioeconomic status. According to Muniyandi's study prevalence tuberculosis higher in those who are living below poverty line.[19] In our study higher incidence of antenatal complication like preterm labour, anaemia, IUGR, ARDS, retroviral disease and threatened abortion have been reported in women with tuberculosis. Treatment of extra-pulmonary tuberculosis had less positive prognosis because their greater difficulty in diagnosis and treated with anti TB early, however maternal outcome can be positive.[6] Extra pulmonary associated with higher rate of hospitalization, low birth weight and poor APGAR score.[36] Higher incidence of prematurity, fetal growth restriction, small for gestation increase risk of neonatal mortality associated with tuberculosis.[1] Similar outcome seen in this study. According to Alene et al MDR-TB and second-line TB medication on adverse maternal and birth outcomes such as prematurity, low birth weight and small for gestational age, and various other obstetrical and perinatal outcomes.[23] In this study significant association was seen in patients of tuberculosis with HIV infection. Similar observation seen in El Messidi et al study.[28] According to Pilay et al study in countries where TB and HIV prevalence is high, efforts to improve maternal and perinatal health must include the detection of TB in pregnancy.[29] Majority of the cases were delivered vaginally i.e., 59 cases **(**56.19%) whereas 13 cases (12.38%) delivered by LSCS. There were 28 (26.66%) Preterm vaginal delivery. This difference was found to be statistically significant ($p<0.00001$). Both groups had vaginal delivery as most common mode of delivery. it was seen that the cesarean section rate was highest in antenatal women without tuberculosis i.e., 67 cases (31.90%) and it was less in antenatal women with tuberculosis i.e., 13 cases. (12.38%) This difference was found to be statistically significant. According to BJOG meta-analysis Caesarean section was performed twice as often in women with TB. The rate of miscarriage were nine times greater in women with TB as compared with antenatal without tuberculosis.[2]

It was observed that in control group 144 (68.57%) had normal birth weight range and 66 (34.29%) had low birth weight. Where as in study group (cases) about 65.71% were low birth weight and 31.43% were normal birth weight and this difference was statistically significant. Low birth weight was seen as one of the adverse outcomes of patients with TB by Loto et al.[1] The prognosis of foetal outcome depends upon the time of diagnosis of tuberculosis. In present study 23 antenatal women diagnosed with tuberculosis in first trimester, one had still birth (4.34%) while 36 women diagnosed with tuberculosis in second trimester 1 neonatal death and 7 still birth were reported. In third trimester, 24 antenatal women were diagnosed with tuberculosis and of these 6 still birth, 6 neonatal deaths reported. Hence, we conclude that early diagnosis and proper treatment will improve the outcome in antenatal women with tuberculosis.

In the study group 18.10% of the cases needed NICU admission where as 8.57% of the controls needed NICU admission and this difference was statistically significant. Low birth weight (57.89%) was the most common reason for NICU admission followed by respiratory distress syndrome (36.84%) in study group. In our study increase risk of NICU admission, small for gestation age and perinatal mortality in pregnant women with tuberculosis. Perinatal morbidity was similar in pregnant women receiving anti tuberculous drugs early during pregnancy to that in uninfected women. The proportion of live foetal outcome among antenatal with tuberculosis was 76.19% and 93.33% among antenatal women without tuberculosis and this difference was statistically significant. The proportion of stillbirth and abortion in case group was 23.81% whereas in control 6.67%. In our study increase rate of neonatal mortality was seen in antenatal women with tuberculosis, similar result was seen in Yadav et al study, Sharma et al study and Chopra et al study.[17,11.35] The death rates among antenatal women with tuberculosis cases were 13.33% and among the controls were 1.43% and this difference was significant. According to Gupta et al study maternal mortality rate was 12.5%.[38] According Ahmed et al study tuberculosis most common non obstetric cause of maternal mortality.[37]

### *Limitations*

The limitation of this study was that the outcome was measured only up to delivery but patient was not followed up till six weeks of puerperium period.

## CONCLUSION

The prevalence rate of tuberculosis in antenatal women at our institute during study period was 2.019/1000 per pregnant women. Our study shows the higher risk of preterm labour, anaemia, ARDS, retroviral disease, threatened abortion and intrauterine growth restriction with tuberculosis in pregnancy. In our study, we found that maternal and perinatal outcome in pregnant women with tuberculosis depends on site, severity of disease, gestation at diagnosis and complication of tuberculosis. Tuberculosis has adverse effect on maternal and fetal outcome So, contraception should be eminently recommended to females in reproductive age bracket with tuberculosis on treatment. Early diagnosis of maternal tuberculosis is the biggest hurdle in management of tuberculosis in pregnancy. So, clinician especially in high burden areas with limited resources like India should utilize available health resources like

antenatal care programme to have patient centered approach in diagnosis, counselling and management of tuberculosis in pregnancy. A high suspicion is required to acknowledge the varying disease spectrum and thus complications of tuberculosis in antenatal women and initiate treatment early for better outcomes. Pre conceptional counselling and early antenatal visits are important opportunities to screen and diagnose TB early in its coarse and ensure adequate treatment as per national programme. This will optimize the maternal and perinatal outcome.

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