
**"INCIDENCE OF TUBERCULOSIS AMONG
HOUSEHOLD CONTACTS ON TUBERCULOSIS
PREVENTIVE TREATMENT- A LONGITUDINAL
STUDY"**

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LIST OF ABBREVIATIONS USED

S. No.	Abbreviations	Expansion of the Abbreviations
1.	TB	Tuberculosis
2.	HIV	Human Immunodeficiency Virus
3.	AIDS	Acquired Immune Deficiency Syndrome
4.	TBI	Tuberculosis Infection
5.	WHO	World Health Organization
6.	LTBI	Latent Tuberculosis Infection
7.	HRG	High Risk Groups
8.	TPT	Tuberculosis Preventive Treatment
9.	SEA	South- East Asia
10.	PLHIV	People Living with HIV
11.	aHR	Adjusted Hazard Ratio
12.	TST	Tuberculin Skin Test
13.	IGRA	Interferon-Gamma Release Assay
14.	AOR	Adjusted Odds Ratio
15.	UOR	Unadjusted Odds Ratio
16.	CI	Confidence Interval
17.	PTB	Pulmonary Tuberculosis
18.	DALY	Disability Adjusted Life Years
19.	DRTB	Drug Resistant Tuberculosis
20.	HHC	Household contact
21.	NTEP	National TB Elimination Program
22.	IQR	Inter Quartile Range

23.	BMI	Body Mass Index
24.	SES	Socio Economic Status
25.	DM	Diabetes Mellitus
26.	CXR	Chest X- Ray
27.	KAHER	KLE Academy of Higher Education and Research
28.	IEC	Institutional Ethics Committee
29.	JNMC	Jawaharlal Nehru Medical College
30.	DTC	District Tuberculosis Centre
31.	PMTPT	Programmatic Management of Tuberculosis Preventive Treatment
32.	IPT	Isoniazid Preventive Therapy
33.	IP	Intensive Phase
34.	CP	Continuation Phase
35.	aPR	Adjusted Prevalence Ratio
36.	CPI	Consumer Price Index
37.	BCG	Bacillus Calmette- Guerin
38.	MF	Multiplication Factor
39.	DSTB	Drug Sensitive TB
40.	IDIs	In Depth Interviews
41.	CBNAAT	Cartridge Based Nucleic Acid Amplification Test
42.	Hb	Heamoglobin
43.	SD	Standard Deviation
44.	GLMM	Generalized Linear Mixed Model
45.	PUC	Pre-University Course

46.	BG	Brahm Govind
47.	MTB	Mycobacterium Tuberculosis
48.	PPD	Purified Protein Derivative
49.	MW	Mann- Whitney
50.	MC	Monte- Carlo
51.	%	Percentage
52.	=	Equal to
53.	>	Greater than
54.	<	Lesser than
55.	$\geq$	Greater than or Equal to
56.	$\leq$	Lesser than or Equal to

ABSTRACT

“INCIDENCE OF TUBERCULOSIS AMONG HOUSEHOLD CONTACTS ON TUBERCULOSIS PREVENTIVE TREATMENT- A LONGITUDINAL STUDY”

Background:

Tuberculosis (TB) is a severe infectious disease that significantly impacts global health.¹ Molecular fingerprinting studies have provided the evidence that the probability of developing the disease among infected is 45% within the first year, 62% within two years, and 83% within five years.⁶ For the majority who receive Tuberculosis Preventive Treatment (TPT), their overall health is good, making it imperative to ensure minimal side effects from the treatment to maintain their adherence.¹⁰.

Objective:

To determine the incidence of tuberculosis among household contacts undergoing tuberculosis preventive treatment.

Methods:

A longitudinal study was conducted from 1st October 2022 to 31st March 2024 among 143 newly diagnosed pulmonary tuberculosis patients and 502 household contacts (HHC) who were chosen using universal sampling method from District Tuberculosis centre (DTC), Belagavi. After enrolling Index cases for the first 6 months, HHC were screened based on TPT guidelines⁶, eligible participants were

initiated on 6 months Isoniazid prophylaxis treatment and follow- up was done to find the TB and TPT outcomes as well as associated factors till 31st March 2024.

Results:

Out of 625 participants, 50.85% were males, majority (64.07%) under the age of 40 years. 37.67% and 40.78% participants were living in well- ventilated houses and in the houses with overcrowding respectively. 15.04% participants were illiterates, 34.11% participants were employed and majority (82.94%) belonged to socio economic class II and III. Among 143 TB patients who were initiated on TB treatment, treatment success (cured+ completed), treatment failure and loss to follow- up was seen in 72.73%, 2.8% and 3.5% participants respectively. Among 502 household contacts who were started on TPT, 93.83% participants had completed the treatment, 2.59% discontinued the treatment due to toxicity, loss to follow- up was seen in 1.79% participants, 0.99% participants developed tuberculosis (TB incidence) indicating treatment failure. Participants with high literacy status were 0.0431 times less likely and who completed the TB treatment were 1.051 times more likely to have successful tuberculosis treatment outcomes. With increase in BMI, participants were 1.0546 times more likely, with completion of $\geq 80\%$ of the treatment, participants were 1.4278 times more likely and with increase in number of treatment discontinuation periods, the participants were 0.51 times less likely to have successful outcomes. After adjusting the factors for TB patients (Generalized linear mixed model), it was found that, increasing age, increase in duration between index case diagnosis and TPT initiation in HHC and index cases with unsuccessful TB outcomes lead to unsuccessful TPT outcomes among household contacts.

Conclusion:

The Incidence of TB among the HHC was 0.99%. TPT can be considered effective in preventing the development of active tuberculosis as indicated by the low incidence of TB cases in household contacts of TB patients. After adjusting the factors for TB patients (Generalized linear mixed model), it was found that, increasing age, increase in duration between index case diagnosis and TPT initiation in HHC and index cases with unsuccessful TB outcomes lead to unsuccessful TPT outcomes among household contacts.

Keywords:

Incidence, Tuberculosis, Household contacts, Tuberculosis preventive treatment.

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INTRODUCTION

Tuberculosis (TB) is a severe infectious disease that significantly impacts global health. Historical records indicate that TB has been afflicting human populations for over 15 thousand years.¹ Despite being both preventable and treatable, tuberculosis emerged as the infectious disease causing the second highest mortality globally in 2022, surpassed only by COVID-19. Mortality caused due to TB was almost twice as high as that from HIV/AIDS.² Annually, tuberculosis affects more than 10 million individuals globally, leading to the deaths of approximately 1.5 million people.^{2, 3} Current estimates suggest that *M. tuberculosis* has infected approximately one-fourth of the global population.⁴ In the year 2022, it was estimated that around 10.6 million individuals globally contracted tuberculosis, including 5.8 million men, 3.5 million women as well as 1.3 million children. The worldwide incidence rate was estimated at 133 new cases per 100,000 people, with deaths reaching approximately 1.30 million.^{2,}

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Tuberculosis is transmitted when droplets containing the *Mycobacterium tuberculosis* bacterium are inhaled. These droplets are expelled by individuals with active TB during coughing or sneezing. Factors that heighten the risk of contracting TB include prolonged exposure to bacteria, high levels of bacterial virulence and load, and compromised immune defense system.^{2,5} Following initial exposure to TB, individuals face the greatest likelihood of disease progression within the initial two-year period, with an estimated risk of around 5%. For individuals with a more chronic infection, the risk is sustained at an estimated annual rate of 10-20 cases per 100,000 individuals.²

India is recognized as having the largest projected number of tuberculosis infections (TBI) globally. Approximately 350 to 400 million individuals in India are believed to be infected with TBI, which results in roughly 2.6 million incident TB cases each year.⁶ The National TB Prevalence Survey, which took place from 2019 to 2021, estimated that the prevalence of tuberculosis is 312 individuals per 100,000 in the population.⁷

A variety of determinants have been identified as significant contributors to the global incidence of new tuberculosis (TB) cases: undernutrition was associated with 2.2 million cases, HIV infection with 0.89 million, alcohol use disorders with 0.73 million, smoking with 0.70 million, and diabetes with 0.37 million, according to the 2022 global report and collectively these risk factors represent 44% of all newly diagnosed TB cases.^{4,7} Approximately 50% of individuals affected by tuberculosis (TB), along with their households, endure significant economic hardship. The sum of their healthcare-related expenditures, non- medical costs, and income loss frequently surpasses 20% of their yearly family earnings. This situation is far from the World Health Organization's (WHO) End TB Strategy, which aims for no patients to incur such catastrophic expenses.^{2,4}

This highlights the urgency for accelerated advancements in universal healthcare and more robust social protection frameworks. Addressing the fundamental factors contributing to TB is essential for overcoming various obstacles and attaining set goals. Intersectoral initiatives are vital for decreasing the incidence and progression of TB infections, thereby reducing mortality rates associated with the disease.²

The presence of *Mycobacterium tuberculosis* does not necessarily result in illness for all carriers. This results in two distinct conditions: Latent TB Infection

(LTBI), which is a state of harboring the bacterium without displaying any active disease symptoms, and TB Disease, where the bacteria are active and cause illness in the host.⁸ Generally, an estimated 5-10% of individuals carrying TB will manifest the disease at some or the other point in their lives, particularly within the first 2 to 5 years following infection, with the possibility of this percentage increasing to 10-15%. The likelihood of developing TB is more than 25-fold for individuals who have been in contact with patients with confirmed TB infections, in comparison to the general population. The risk escalates by 16-21 times for those who also have HIV. Moreover, people with weakened immunity, such as diabetes patients, are at a 3-4 times greater risk of developing TB.^{5,6}

Studies show that three-quarters of people who develop TB disease after being exposed to someone with active TB will likely become ill within the first year following the initial patient's diagnosis. It is also projected that 97% of such cases will occur within two years. Molecular fingerprinting studies have provided evidence supporting these estimates, indicating that the probability of developing the disease is 45% within the first year, 62% within two years, and 83% within five years.⁶

The prompt identification and management of TB disease remains a critical priority in India. Equally vital is the prevention of TB, which involves detecting and treating Tuberculosis Infection (TBI) and proactively searching for cases among High-Risk Groups (HRGs) to effectively combat the TB spread. Epidemiological research suggests that the sole application of Tuberculosis Preventive Treatment (TPT) within the South-East Asia (SEA) region has the potential to reduce the annual TB incidence rate by 8.3%, independent of any other simultaneous measures.⁹

Addressing Tuberculosis Infection (TBI) to avert the onset of TB disease is a key component of India's National Strategic Plan 2017-25 aimed at eradicating TB. The plan endorses a comprehensive approach of Detection, Treatment, Prevention, and Construction of healthcare infrastructure. Intensifying Tuberculosis Preventive Treatment (TPT) efforts, alongside meticulous TB contact tracing and examination, is imperative to hasten the decline in the incidence of TB from the present rate of 2.5% to the target rate of 10% annually.^{6,7}

It is crucial to amplify and broaden initiatives and funding to improve the provision of Tuberculosis Preventive Treatment (TPT). This includes escalating TB testing within homes and refining the subsequent follow-up processes and continuum of care, not only in domestic settings but also for Individuals Living with HIV (PLHIV).^{2,6} For the majority who receive Tuberculosis Preventive Treatment (TPT), their overall health is good, making it imperative to ensure minimal side effects from the treatment to maintain their adherence. TPT medications are generally considered safe with a good tolerance profile. However, there have been reports of side effects from isoniazid, such as liver enzyme elevation, nerve damage, and liver toxicity, as well as from rifampicin and rifapentine, which include allergic skin reactions, hypersensitivity, digestive issues, and liver toxicity. Although these side effects are rare and usually minor, it is essential to carefully monitor and prevent any liver damage that could result from the medication.¹⁰

Considering the suboptimal continuum of care, challenges with treatment adherence, insufficient medication availability, and various other issues, this study was planned to determine the incidence of tuberculosis among household contacts undergoing tuberculosis preventive treatment.

OBJECTIVE OF THE STUDY

To determine the incidence of tuberculosis among household contacts on tuberculosis preventive treatment

REVIEW OF LITERATURE

A systematic review and meta-analysis conducted in 2023 to assess the efficacy of tuberculosis preventive treatment across various age groups and infection statuses among 539644 individuals across 32 cohort studies by including the studies published from January 1, 1998, to April 6, 2018 revealed that, a total of 2,496 individuals were diagnosed with tuberculosis. The effectiveness of the preventive treatment was determined to be 49% (with an adjusted hazard ratio [aHR] of 0.51 [95% CI: 0.44–0.60]). Enhanced protection was observed in those who tested positive on the baseline tuberculin-skin-test (TST) or interferon-gamma release assay (IGRA), regardless of age. Specifically, the aHR was 0.09 (95% CI: 0.05–0.17) for children under the age of 5, 0.20 (95% CI: 0.15–0.28) for those aged 5–17 years, and 0.17 (95% CI: 0.13–0.22) for adults aged 18 and above. In high TB burden settings, the treatment's efficacy was more significant (aHR 0.31 [95% CI: 0.23–0.40]) in comparison to low-burden settings (aHR 0.58 [95% CI: 0.47–0.72]). The study concluded that in areas with less TB burden, a focused approach targeting individuals with a confirmed *M. tuberculosis* infection might be more appropriate, whereas in high-burden areas, a more inclusive strategy that covers all contacts could be beneficial.¹¹

A Cross-sectional study conducted in 2023 among 301 household contacts of index cases registered at a TB unit in Murshidabad district, West Bengal, between October 2022 and March 2023 to evaluate the coverage and adherence to tuberculosis preventive treatment (TPT), identify reasons for non-initiation and non-adherence, and explore socio-demographic and programmatic factors influencing coverage showed that, out of 301 individuals, 179 (59.5%) received individual tracing and counselling at their residences, and 238 (79.1%) were screened for the disease, with

28 (11.3%) undergoing sputum tests. The rate of TPT initiation was 74.8% (225/301), with 47.1% beginning their treatment within a week of the index case's diagnosis. The main reason cited by 59.2% for not starting treatment was that it wasn't provided by the healthcare workers. Of those who began TPT, 69.3% (156/225) adhered to the complete course, with the lack of perceived need (50.7%) and migration (21.7%) being the primary reasons for discontinuation. The total coverage of the complete TPT course among all suitable contacts was only 51.8% (156/301). The multivariable logistic regression analysis revealed significant associations for higher TPT coverage with the male gender (adjusted odds ratio [AOR] = 1.982; 95% confidence interval [CI] = 1.004–3.915), contacts who had individual tracing/counselling (AOR = 13.507; 95% CI = 6.781–26.906), and those screened for symptoms (AOR = 5.694; 95% CI = 2.223–14.587). The study concluded that the indicators for TPT care cascade are not at the desired levels in the area, pointing to a need for improvements in the programmatic aspects of TPT delivery.¹²

A Retrospective cohort study carried out at King Fahad Medical City in Riyadh, Saudi Arabia between 2018- 2023 among 427 pulmonary TB patients to assess the obstacles with the goal of informing more effective treatment and management strategies found that, a significant majority, 88.5% of the individuals experienced positive outcomes following treatment. The data analysis pointed out that the likelihood of treatment non-success was greater in male patients when compared to their female counterparts, with the figures showing an adjusted odds ratio (aOR) of 1.3 and a confidence interval (CI) of 95% ranging from 1.2 to 1.5 (p-value < 0.001). Moreover, the study identified two factors that were associated with an increased risk of treatment non-success: the existence of a positive sputum smear test (aOR 1.3; 95% CI 1.1–1.3, p-value < 0.001) and the presence of a cough (aOR 1.5; 95% CI 1.1–1.4,

p-value < 0.001). The research concluded with the finding that the patients with unsuccessful treatment outcomes stood at 11.5%, a figure that was primarily due to patient deaths and instances of patients not continuing with the treatment.¹³

A mixed-methods study conducted among 14,133 participants in 2022-2023 to evaluate the "Test and Treat" approach of Tuberculosis Preventive Treatment (TPT) care cascade for household contacts (HHCs) aged 5 years and above of pulmonary tuberculosis (PTB) patients who were either bacteriologically or clinically confirmed and were receiving TPT care under the Project Axshya Plus in Maharashtra, India, revealed that, from a total of 4,181 primary TB cases, 14,172 household contacts (HHCs) were evaluated, leading to the identification of TB in 36 (0.3%) HHCs. Of the 14,133 HHCs considered suitable for further testing, 10,777 (76.3%) were subjected to the Interferon-Gamma Release Assay (IGRA) test, out of which 2,468 (22.9%) returned positive results and were recommended for a chest X-ray examination. From the 2,353 HHCs who were eligible, 2,159 (91.7%) initiated Tuberculosis Preventive Treatment (TPT), and among them, 1,958 (90.6%) successfully completed the treatment course. The median time span from starting treatment in the index Pulmonary Tuberculosis (PTB) patient to (a) screening of HHCs was 31 days, and (b) commencement of TPT was 64 days. The study pinpointed various challenges and proposed solutions for better TPT care process, focusing on aspects such as testing for TB infection, the accessibility of chest X-rays, distribution of human resources, enhancing awareness and participation, bettering healthcare facility access, ensuring the supply of TPT drugs, consistent patient follow-up, and comprehensive evaluations. The study concluded that regular monitoring and prompt assessment regarding TPT care delivery, along with immediate interventions,

are crucial for its successful execution and, consequently, for effective TB prevention.¹⁴

A state-transition model was utilized to simulate the impact of short-course TB preventive therapy (TPT) for household contacts and people living with HIV (PLHIV) by incorporating data from 29 high-incidence countries, sourced from prior studies and public databases, to determine the cost-effectiveness of TPT. The research indicated that from 2023 to 2035, the expansion of TPT might avert approximately 0.9 TB cases (95% uncertainty interval: 0.4–1.6) and 0.13 TB-related fatalities (0.05–0.27) per 100 individuals with HIV, at an additional cost of \$15 (9–21) per person. Related to household contacts, the combined approach of TPT and contact investigation is projected to prevent 1.1 (0.5–2.0) TB cases and 0.7 (0.4–1.0) deaths per 100 individuals, with an extra expense of \$21 (17–25) each. The cost-effectiveness analysis revealed the most favourable outcomes for young household contacts under five years old, with a cost of \$22 per DALY saved, and for those aged 5–14, at \$104 per DALY saved. These figures fall within the globally recognized cost-effectiveness thresholds for people living with HIV (\$722 per DALY saved) and adult contacts (\$309 per DALY saved). When compared to scenarios that only included contact investigation without TPT, the expenditure per DALY saved was generally more economical. Sensitivity analyses underscored the sustained cost-effectiveness of TPT, especially when considering extended periods or the benefits of halting secondary transmission. The study concluded that in many high-TB-burden nations, a brief TPT regimen could be a cost-effective measure for both people living with HIV and household contacts of all ages, irrespective of existing contact investigation measures. Without the implementation of contact investigation and TPT

implementation, a significant preventable burden of disease and mortality is anticipated over the next decade.¹⁵

A cohort study carried out among 297 child contacts from October 2021 to September 2022 in Bishkek, Kyrgyz Republic to evaluate the continuum of care focusing on TB screening, diagnosis, and initiation of both anti-TB treatment and TPT revealed that, among 873 individuals with TB, only 153 (18%) had recorded instances of child contacts. Out of the 297 children pinpointed, 285 presented complete records. A total of 261 children (92%) were screened for TB, yet notably, half of these screenings were postponed, taking place over a month subsequent to the initiation of the patient's TB treatment. Within the group of 285 children, 23 (9%) were diagnosed with TB. Among the 238 children who were not diagnosed with TB, 130 (55%) were considered eligible for Tuberculosis Preventive Treatment (TPT). From this subgroup, 64 children (49%) began TPT, and of those, 52 (81%) successfully completed the regimen. The study concluded that despite a high rate of TPT completion, there were considerable lags in the processes of contact tracing, screening, and starting TPT.¹⁶

A Cross-sectional study carried out in 2022 encompassing all registered patients with pulmonary tuberculosis (TB) and their 1372 immediate contacts in central Ethiopia to evaluate the implementation of contact investigation and adherence to tuberculosis preventive treatment revealed that, 79.44% (1090) of the contacts received a single TB screening, uncovering four (0.36%) cases of active TB. Within the subgroup of 484 contacts linked to drug-resistant TB (DR-TB) cases, 5.53% (14) were deemed presumptive TB cases, and 0.79% (2) were confirmed as active TB cases. Conversely, of the 837 contacts associated with drug-susceptible TB cases, 1.91% (16) were considered presumptive TB cases, and 0.23% (2) were diagnosed with active TB. Among 142 children eligible for preventive treatment, 81.69% (116)

started the treatment, and 84.48% (98) saw it through to completion. The multivariable logistic regression analysis indicated a significant link between non-compliance with TB preventive treatment and the age groups 2–5 years (aOR 0.02; 95% CI 0.002–0.20) and 5–15 years (aOR 0.04; 95% CI 0.002–0.95), both with P-values below 0.05. The study concluded that the screening practices for contacts of DR-TB cases fell short of national and international standards, pointing to a pressing need to enhance the efficacy of routine contact screenings.¹⁷

A mixed-method study carried out among 301 index patients in the Kolar district of Karnataka in 2022 to evaluate the tuberculosis preventive treatment (TPT) cascade and identify early barriers to implementing TPT revealed that, contact tracing home visits were executed in 247 instances (82.1%). A notable barrier was the hesitance of primary patients to consent to these visits, driven by stigma fears, among those receiving treatment privately. Among 838 household contacts (HHCs), 765 (91.3%) underwent TB screening. The process was hindered by ambiguities regarding the definition of HHCs and their frequent non-availability during visits. Out of 692 HHCs qualified for testing, only 400 (57.8%) received the Interferon-Gamma Release Assay test for TB infection (TBI); the main hurdles being logistical constraints for IGRA testing and a low perceived risk by HHCs. The lack of communication about IGRA outcomes meant the precise number of HHCs eligible for TPT remained indeterminate. From the 83 HHCs recommended to start treatment, 81 (98%) participants initiated the therapy, with 63 (77%) completing it. The study concluded that despite high rates of initiation and completion of TPT, the National Tuberculosis Elimination Program (NTEP) needs to promptly tackle the issues in investigation of contact and IGRA testing to enhance the effectiveness of the program.¹⁸

A Systemic review and meta-analysis conducted by including 58 studies from 23 countries to summarize the management strategies for latent tuberculosis infection (LTBI) among household contacts of individuals with bacteriologically confirmed pulmonary TB in countries with a high TB burden by including the studies published from January 2006 to December 2021 that provided primary data on LTBI management revealed that, the vast majority of contacts identified were screened (median 99%, interquartile range [IQR] 82%–100%; from 46 studies). The meta-analysis using a random-effects model showed combined rates for LTBI at 41% (95% CI 33%–49%; from 21,566 tested contacts); commencement of TPT at 91% (95% CI 79%–97%; from 129,573 eligible contacts, in 34 studies); and TPT completion at 65% (95% CI 54%–74%; from 108,679 contacts who started TPT, in 28 studies). The variation in results was significant ($I^2 \geq 95\%$ –100%) and persisted beyond subgroup analyses. Median rates (IQR) were as follows: LTBI at 44% (28%–59%); initiation of TPT at 86% (60%–100%); and TPT completion at 68% (44%–82%). The study identified nine key themes, such as diagnostic testing, structure of health system and efficiency, perception of risk, record-keeping, and compliance, as potential factors affecting the LTBI treatment process. The study concluded that despite high rates of screening, detection of LTBI, and start of TPT among household contacts, the completion rates for TPT are considerably lower, indicating that current LTBI management approaches in countries with high TB incidence might be falling short.¹⁹

A prospective study conducted among 360 new patients in 2021- 2022 with sputum-positive pulmonary tuberculosis at the Department of Respiratory Medicine, GMC Kannur to evaluate the socio-demographic profile and Body Mass Index (BMI) of these patients, as well as the outcomes of their treatment, to understand the relation between low socioeconomic status (SES) and new smear-positive pulmonary

tuberculosis (PTB), the prevalence of malnutrition among PTB patients, and the impact of malnutrition and low level SES on treatment outcomes showed that, 29.2% of the individuals were within the 41-50 year age group, with males outnumbering females at a ratio of 1.7:1. Socio-demographically, 93.3% were native residents, and 72.2% were in matrimonial unions. A considerable 81.9% were from lower social strata, while 94.7% were part of nuclear family setups. Predominantly, families were of smaller size, with 70% being classified as such, and the majority of them, 87.2%, resided in permanent dwellings. Elementary education was prevalent, and the education level was notably low at 1.9%. Among those with positive sputum tests, 43.3% were categorized under low socio-economic status (SES). Malnutrition, indicated by a BMI below 18.5 kg/m^2 , was found in 58% of the cohort. Notably, there was a significant rise in BMI ($p < 0.001$) after treatment. Diabetes Mellitus (DM) emerged as the most common accompanying health issue, present in 38.9% of the cases. Following treatment, there was a marked improvement in chest X-ray (CXR) results ($p < 0.001$). The study identified that DM (Odds Ratio (OR) = 0.367, 95% CI = 0.181-0.742, p -value = 0.004), smoking habits (p -value = 0.006), and the presence of CXR shadows (OR = 0.190, 95% CI = 0.079-0.460, p -value = 0.001) significantly influenced the rates of sputum smear conversion. The study concluded that smoking, DM, and CXR findings are influential factors in sputum smear conversion after two months, which is a important measure of infectiousness.²⁰

A mixed-methods study was conducted among all HHC of newly diagnosed pulmonary TB patients at three selected District Tuberculosis Centers (DTC) in Delhi in 2022 to evaluate the early stages of implementing the Programmatic Management of Tuberculosis Preventive Treatment (PMTPT). The study revealed that despite having a structured plan and organizational setup ready, the practical application of

preventive therapy encountered several obstacles. These included difficulties in obtaining medications, financial limitations, a shortage of staff, and gaps in training. On the positive side, factors such as heightened awareness, motivation, shorter treatment options, phone-based evaluations, and collaborations with NGOs contributed to the process. However, the adoption of TPT was hindered by apprehensions about initiating treatment, fluctuating drug supplies, the protracted duration of treatment, side effects, system burdens, the sheer number of people involved, resistance to the drug isoniazid (INH), data management issues, and reluctance from private sector health providers. The study's conclusion pointed out the urgent need for viable strategies to improve TPT implementation. While progress has been made in introducing TPT, there is considerable room for improvement and refinement in various aspects.²¹

A mixed-method study carried out in 2021 among 280 children who had been in contact with tuberculosis (TB) cases registered from January to December 2020 across all TB units within the Paschim Bardhaman District of West Bengal, India to evaluate the coverage and adherence levels of Isoniazid Preventive Therapy (IPT), identify its sociodemographic and programmatic determinants, and uncover the challenges faced by service providers and beneficiaries found that, screenings were conducted for 48.9% (137/280) of the child contacts; 58.9% (165/280) initiated Isoniazid Preventive Therapy (IPT), with 40% (66/165) completing the therapy. The completion rate of IPT over a six-month period was at 23.6% (66/280) among the children. Key determinants for improved IPT uptake included home visits by medical personnel and early screening efforts. The research identified multiple obstacles to IPT coverage, such as systemic issues, knowledge gaps, social stigma, and disruptions due to the COVID-19 pandemic. The findings concluded that there is a urgent need

for health system improvements to improve the execution of advised strategies for TB preventive treatment.²²

A population-based cross-sectional study carried out among 984 individuals who had been in contact with LTBI cases reported in Catalonia between 2019 and 2021 to find the factors linked to the non-compliance with tuberculosis (TB) preventive therapy revealed that, within the group, the proportion of individuals not adhering to TPT was 23.7%. The multivariable logistic regression analysis determined that a number of factors significantly influenced the lack of adherence among adult contacts: being in educational or work environments (adjusted Odds Ratio (aOR) = 3.34), having been in contact with a TB case not verified by lab tests (aOR = 2.07), immigrant status (aOR = 1.81), male gender (aOR = 1.75), and exposure to TB for less than 6 hours weekly or occasionally (aOR = 1.60). But, choosing a "short-term TB preventive treatment regimen" was associated with a notable increase in adherence (aOR = 0.38). The research concluded that to improve adherence to TB preventive measures in adults with latent TB infection, it is beneficial to encourage short-duration treatment regimens and create specific health education programs, particularly for those at higher risk of non-adherence.²³

A facility-based mixed-method study carried out in 2021 among 392 pulmonary tuberculosis patients and 23 key informants to assess the adherence to household contact tuberculosis screening (HHCS) and its influencing factors among pulmonary tuberculosis (PTB) patients undergoing follow-up in health facilities located in Shashamane Town, Southeast Ethiopia found that, that the total compliance rate was 44.4% with a 95% Confidence Interval (CI) of 39.3 to 49.1. The study found significant associations between adherence to screening of Household Contacts (HHCS) and several factors: contacts being younger than fifteen years old (Adjusted

Odds Ratio (AOR) = 2.386, 95% CI: 1.44 to 3.96), having at least a diploma education (AOR = 3.43, 95% CI: 1.286 to 9.15), exhibiting substantial knowledge (AOR = 2.999, 95% CI: 1.79 to 5.03), possessing a positive attitude (AOR = 2.409, 95% CI: 1.45 to 4.02), being recipients of health education (AOR = 3.287, 95% CI: 1.92 to 5.63), and a diagnosis of smear-positive Pulmonary Tuberculosis (PTB) (AOR = 2.156, 95% CI: 1.28 to 3.62). The study concluded that the level of adherence to HHCS was not up to the desired standards set by WHO and national guidelines, which recommend screening for all household contacts. The age of contacts, educational background, level of knowledge, attitudes, the provision of health education, and the diagnosis of PTB were all identified as factors influencing adherence.²⁴

A cross-sectional study conducted in 2020 among 536 household contacts to determine the intention to accept Tuberculosis Preventive Therapy (TPT) among adult household contacts of pulmonary tuberculosis (PTB) patients in Delhi, India, showed that, 237 were male (44.2%) and 299 were female (55.8%) participants, with a median age of 40 years (IQR: 22-52 years). The study identified several risk factors for developing tuberculosis among these contacts: undernutrition (32.3%), excess weight (47.8%), and concurrent diabetes (10.6%). Notably, a vast majority (97.3%) of the participants lacked awareness of latent tuberculosis infection. Willingness to undergo TPT was indicated by 394 individuals (73.5%), with the main reasons for reluctance being no symptoms (33.1%), feeling of good health (42.9%), and apprehension about side effects from the medication (27.5%, n=142). The study concluded that a significant proportion of household contacts, nearly three-quarters, who don't have TB disease, are ready to start TPT when recommended, though this is tempered by concerns about the influence of social desirability bias.²⁵

A Qualitative study carried out in 2019- 2020, in three primary health clinics in Kota Kinabalu, Sabah State, Malaysia, to examine the elements influencing the execution of TB contact investigation and preventive treatment for children among 34 parents and guardians of children eligible for TB preventive treatment along with 25 healthcare providers managing these child contacts had identified six key themes, with four related to the contact investigation and two associated with TB preventive therapy. The elements influencing the investigation of TB contacts were divided into four categories: system-related factors (like external pressures and collaboration among stakeholders), factors that are related to clinic (such as the clinic's perceived efficacy and logistical issues), factors related to healthcare workers (which include their cooperation, dedication, and expertise), and factors concerning patients and their contacts (highlighting the need for their cooperation and commitment). The administration of TB preventive therapy was affected by factors related to guardians (such as their willingness to cooperate and their level of understanding) and factors related to the treatment itself (including the suitability of the formulations for children and potential side effects). The study concluded that it is crucial to improve the capacity of the health system to carry out consistent contact investigations and preventive treatments, even in the face of risks from external programs.²⁶

A longitudinal study was conducted from 2018 to 2020 at a tertiary care hospital in a major city of Maharashtra among 181 newly diagnosed drug-sensitive pulmonary TB patients to explore the relationship between various socio-demographic factors and adherence to the daily treatment regimen, to identify the patterns and reasons for non-adherence. During the monitoring periods at the 2nd and 6th months of treatment, corresponding to the Intensive Phase (IP) and Continuation Phase (CP), it was observed that of the 181 individuals undergoing treatment, 110 (60.8%) maintained

adherence, whereas 71 (39.2%) did not. Within the group that did not adhere, 64 (90.9%) had instances of skipping doses sporadically, and 7 (9.9%) ceased their treatment completely. The predominant factors for non-compliance were cited as personal obligations and perceived health improvements, with a significant p-value of < 0.0001 . Influential socio-demographic elements that played a role in adherence were identified as the patient's age ($p = 0.013$), education status ($p = 0.035$), the extent of the family unit ($p = 0.018$), history of TB in the family ($p = 0.0001$), and whether the patient smoked ($p = 0.025$). The research concluded that these socio-demographic variables have a considerable impact on the levels of treatment adherence. Having a family history of TB disease and the result of sputum conversion at the conclusion of the CP were significant independent predictors for non-adherence in patients with pulmonary TB.²⁷

A Programmatic review of TPT was conducted in 2019- 2020 to find the reasons for poor uptake of preventive therapy in South Africa among 134 informant interviews, 93 semi-structured observations, and reviews of TB patient folders in 31 health facilities across the Western Cape, Eastern Cape, and KwaZulu-Natal found that, suboptimal execution of the Tuberculosis Preventive Treatment (TPT) program, marked by a lack of thorough oversight, even in regions where TB services were otherwise deemed efficient. Health professionals displayed reservations about the effectiveness of TPT, often relegating it to a lower status in their practical duties, and opinions varied regarding the assignment of responsibility for its execution. Service and facility-related hurdles encompassed inadequate contact tracing procedures, constrained resources, a lack of uniform reporting protocols, and insufficient education for patients about TPT. On the individual level, socio-economic challenges significantly impeded patient engagement. The research concluded that, to improve

the application of TPT, there is a necessity for more streamlined and user-friendly systems, as well as extensive training for medical staff at all tiers. Additionally, establishing collaborative relationships with community groups to encourage service utilization driven by community needs could enhance the overall effectiveness of TPT deployment.²⁸

A Retrospective cohort study conducted in 2019- 2020 among 341 HIV patients selected at random who were started on isoniazid preventive Therapy in Kampala, Uganda to assess the completion rates of IPT, identify factors contributing to non-completion, and explore the patients' perceived obstacles to completing the treatment revealed that, 69% were female participants (236 out of 341 patients), the study recorded an 83% rate of completion for IPT. The multivariate analysis revealed that male patients had a 2.24 times higher probability of not completing IPT than their female counterparts (adjusted prevalence ratio [aPR] 2.24, 95% confidence interval: 1.40–3.58, $p = 0.001$). For patients with uncontrolled HIV viral loads, the risk of IPT non-completion was tripled compared to those with controlled viral loads (aPR 3.00, 95% CI: 1.44–6.65, $p = 0.007$). Moreover, those who were married or in a partnership showed a 69% reduced incidence of not finishing IPT compared to single individuals (aPR 0.31, 95% CI: 0.17–0.55, $p < 0.000$). Reported obstacles to completing IPT included a lack of adequate information about the therapy, difficulties in juggling various medications, travel distance to medical centers, and relocation necessities. The study concluded that while the overall IPT completion was high, specific groups, particularly males and patients with high HIV viral loads, had lower completion rates. The research underscores the importance of specialized interventions to overcome these barriers and enhance IPT completion rates, especially in the identified subgroups.²⁹

A cohort study conducted among 420,854 household contacts of 137,131 tuberculosis (TB) index patients to ascertain the incidence and to explore the socioeconomic and clinical factors influencing TB by including TB contacts diagnosed from January 1, 2004 to December 31, 2018 who were monitored until either a subsequent TB diagnosis, death or the end of the study revealed that, they tracked participants over a 15-year period, with a median follow-up of 4.4 years (IQR 1.9–7.6), during which 8,953 contacts were diagnosed with TB. The TB incidence rate among these contacts was 427.8 per 100,000 person-years (95% CI 419.1–436.8), a figure 16 times greater than the incidence rate in the broader population, which stands at 26.2 per 100,000 (95% CI 26.1–26.3). This disparity underscores an extended risk period. The study found a significant association between TB incidence and contacts of index patients who were either preschool-aged (<5 years; aRR 4.15 [95% CI 3.26–5.28]) or had pulmonary TB (aRR 2.84 [95% CI 2.55–3.17]). The findings concluded that there is a need to prioritize and strengthen contact tracing and TB preventive treatment measures in Brazil, given the sustained high risk among contacts.³⁰

A Model based analytical study carried out in 2019 to assess the high-risk population for tuberculosis (TB) due to household exposure in countries with high incidence rates from 20 countries, which collectively account for over 80% of the global TB incidents in 2019 among 38 million individuals revealed that, in the studied group, 12% were children below five years old, and 65% were adults. Nations such as Zimbabwe, Mozambique, Zambia, and Pakistan recorded the highest proportions of their citizenry being in contact with TB within households. In contrast, India had the highest actual count of individuals exposed, with an estimate of 11.4 million people (within a 95% uncertainty range of 9.7 to 13.4 million). The research concluded that expanding the scope of TPT assessments to encompass household contacts across all

age groups in regions with high TB incidence could address a demographic more than sevenfold larger than the previously prioritized under-five age group.³¹

A Cross-sectional study was carried out in 2019 involving 279 index cases and 712 household contacts from 8 high TB burden countries to identify factors linked with prevalent *Mycobacterium tuberculosis* infection and disease among adolescents and adults who were exposed to Rifampicin-resistant tuberculosis within their households. The demographic data showed 63% female population, 22% smokers (current), 8% smokers (former), 8% HIV-positive, and 11% with h/o TB treatment. Of the 686 HHCs tested, 471 were found to be IGRA positive, equating to a prevalence of 68.8% and a 95% Confidence Interval (CI) of 64.6% to 72.8%. The multivariable analysis demonstrated a significant association of IGRA positivity with HHCs aged 25 to 49 years, those with prior TB treatment, and individuals with incarceration, substance use, or daily alcohol intake history over the last year. Additionally, IGRA positivity was higher among those in close quarters with the index case, living with smokers, or in lower socioeconomic housing conditions. Moreover, 46 HHCs aged 15 years and older, representing 6.5% (with a 95% CI of 4.6% to 9.0%), were diagnosed with TB disease. The analysis also found a greater occurrence of TB in HHCs over 50 years old, current or past smokers, those with recent regular alcohol use, and individuals with previous TB treatment. The study concluded that certain traits are shared and unique to MTB infection and TB disease, offering valuable insights for those undertaking household TB investigations.³²

A case-control study carried out in the Sidama and Gurage Zones of Southern Ethiopia among 84 cases and 243 controls in 2016- 2017 to identify the risk factors for drug-resistant tuberculosis (DR-TB) among TB patients indicated that, 59% (49 cases) were male participants, while 55% (132 controls) participants were female. The

median age for cases was 28 years (interquartile range of 21–37), and for controls, it was 27 years (interquartile range of 25–33). Factors significantly associated with drug-resistant TB (DR-TB) included residing in a single-room dwelling (AOR: 6.8, 95% confidence interval [CI]: 1.8–25.8), previous exposure to DR-TB cases (Adjusted Odds Ratio: 6.8, 95% CI: 1.8–25.3), history as a treatment failure TB case (AOR: 4.2, 95% Confidence Interval: 1.1–15.5), and relapse in TB cases (AOR: 4.8, 95% CI: 1.3–18.1). The study concluded that the usage of a uniform first-line treatment approach for both new and returning TB patients, coupled with fundamental TB infection control practices, may play a crucial role in curbing the transmission of DR-TB.³³

A Case-control study was conducted 2017 among 260 cases and an equal number of controls to assess the risk factors for tuberculosis in Addis Ababa. The investigation included cases of newly identified pulmonary TB patients confirmed through bacteriological tests, all over 15 years age, from twenty healthcare centers. The control group consisted of individuals of similar age and gender, visiting for health concerns unrelated to TB. The multivariable logistic regression pinpointed seven factors that independently predicted the likelihood of contracting TB, after accounting for other variables. Residing in a dwelling with zero or one window presented nearly twice the risk of TB compared to homes with more windows (AOR = 1.81; 95% CI: 1.06 to 3.07). Prior hospital stays were linked to a more than three times higher risk (AOR = 3.39; 95% CI: 1.64 to 7.03). Having a family member diagnosed with TB increased the risk threefold (AOR = 3.00; 95% CI: 1.60 to 5.62). Non-literate individuals had a more than double probability of TB infection than those with basic literacy skills (AOR = 2.15; 95% CI: 1.05 to 4.40). A household income of < 1000 birrs per month also doubled the risk (AOR = 2.2 with 95% CI: 1.28 to 3.78).

Smoking was a significant risk enhancer, quadrupling the chance of developing TB (AOR = 4.43 with 95% CI: 2.10 to 9.3). In contrast, the BCG vaccine showed a protective effect, minimizing the risk by a third (AOR = 0.34; 95% CI: 0.22 to 0.54). The study concluded that TB mainly impacts the most active and economically contributing demographic. It identified living conditions, medical history, educational status, income level, smoking habits, and inadequate BCG vaccination as independent risk contributors. Therefore, TB prevention strategies should target socioeconomic challenges such as poverty, dense living conditions, and tobacco use, along with enhancing infection control in medical settings to mitigate TB spread.³⁴

A qualitative study conducted in 2015 among 21 participants in Armenia to explore and articulate the elements that contributed to treatment adherence among patients with drug-sensitive tuberculosis (DS-TB) by including 16 in-depth interviews (IDIs) with individuals who had recovered from DS-TB, two IDIs with relatives of these patients, and a group discussion with healthcare professionals responsible for DS-TB patient care identified that, a comprehensive understanding of tuberculosis (TB) and its management, along with patients' personal beliefs about the illness, their confidence in TB-specialized healthcare professionals, and their own sense of responsibility, were the crucial factors which predisposed them to successfully complete their treatment. Additional reinforcing factors were the support and encouragement from medical staff, relatives, and peers, the desire to steer clear of the stigma tied to TB, and positive reactions to TB medication. The ease and simplicity of the TB treatment schedule, coupled with the accessibility and cost-effectiveness of TB healthcare services, served as facilitative factors. The study concluded that these findings provide new insights into what motivates patients to stick with long-term medical treatments such as TB therapy. Implementing strategies that promote patients'

sense of responsibility and positive outlook towards TB, as well as involving their families, could potentially increase the chances of treatment adherence and success.³⁵

MATERIALS AND METHODS

Source of Data

Newly diagnosed pulmonary tuberculosis cases registered under the National Tuberculosis Elimination Program (NTEP) at the District Tuberculosis Centre (DTC), Belagavi, India and Household contacts of these newly diagnosed tuberculosis patients.

Study Design

Longitudinal study

Study Period

1st October 2022 to 31st March 2024.

Study Area

Rural and Urban regions of Belagavi

Sample Size

A total of 645 study participants, that is, 143 pulmonary tuberculosis patients and 502 household contacts were chosen using Universal sampling method.

Method of data collection

Newly diagnosed pulmonary tuberculosis cases registered under DTC, Belagavi, from 1st October 2022 to 31st March 2023 and their household contacts were enrolled as study participants.

Participants were interviewed by using a pre-designed and pre-tested questionnaire after taking informed consent

Information regarding socio-demographic details, symptoms, past history, personal history, treatment history, details of Tuberculosis treatment, details of tuberculosis preventive treatment and related factors were enquired

Physical examination of participants was done followed by primary tuberculosis symptom-based screening where all the household contacts were examined for the presence of fever >2 weeks, cough >2 weeks, night sweats and weight loss

If symptomatic, sputum microscopy or CBNAAT was performed. If asymptomatic, X-ray was performed. Tuberculin skin testing was done in the household contacts aged ≤ 6 years.

Additional Investigations such as Hb%, complete blood count, liver function test, renal function test, and ultrasound were performed for participants with complications (both before and during follow-up).

Household contacts negative for TB disease were initiated on a 6-months tuberculosis preventive treatment regimen (Isoniazid).

Monthly follow-up of both the index cases and household contacts was done until 31st March 2024.

Inclusion Criteria

Newly diagnosed pulmonary tuberculosis (sputum positive or sputum negative/culture positive) patients registered for treatment under NTEP at the District Tuberculosis Centre, Belagavi (1st October 2022 – 31st March 2023).

Household contacts of the index cases who have agreed to take tuberculosis preventive treatment under DTC, Belagavi.

Exclusion Criteria

Household contacts with less than 3 months exposure to the index case.

Contacts with health-related contraindications for Isoniazid medication.

Ethical Clearance

The study received approval from the Institutional Ethics Committee for Human Subjects Research, KAHER, Jawaharlal Nehru Medical College, Belagavi (Ref No. MDC/ JNMCIEC/ 77).

Informed Consent

Written informed consent was obtained from each participant prior to enrollment.

Statistical analysis

Data was analyzed using statistical software R software version 4.1.2 and Microsoft Excel. Categorical variables are given in the form of frequency tables. Continuous variables are given as Mean $\pm$ SD/Median (range). To compare normally distributed continuous variables over a group, t-test was used. To compare non-normally distributed continuous variables over a group, Mann-Whitney test was applied. To check the association between categorical variables, Chi-square test was used. To check the factors affecting successful or unsuccessful treatment outcomes, logistic regression was used. Quasi-binomial distribution was used in the logistic regression model of TPT outcome with other risk factors. P-value less than equal to 0.05 was taken as statistically significant.

Generalized Linear Mixed Model (GLMM) for logistic regression was done by taking Index case number as random effect in the model and completion of treatment status among TPT subjects was taken as response to the model. Univariate GLMM logistic regression results are presented for significant factors affecting the outcome and multiple GLMM logistic regression model was selected using forward selection method.

Definitions of study variables

1. **Age:** Calendar age in years was considered for the study (nearest completed years)

2. **Gender:** Either male or female was mentioned.

3. **Address:** Residential address was taken into consideration.

4. **Occupation:**

Employed: “An occupation by which a person earns a living”.³⁶

Unemployed: “Not engaged in a gainful occupation”.³⁷

5. **Education status:**

Illiterate: “A person who could not read and write any language”.³⁸

Primary school: “A person who had studied from first to seventh standard”.³⁸

High school: “A person had studied 8th standard to 12th standard”.³⁸

PUC or diploma: “Person who has studied up to PUC 2nd year or a Diploma Course”.³⁸

Graduation: “A person who had a bachelor’s degree in any field”.³⁸

6. **Marital status:** Marital status was classified as: married, unmarried, widow, widower, divorcee.

7. **Religion:** “An organized system of beliefs, ceremonies, and rules used to worship a God or groups or Gods. For examples Hindu, Muslims and Christian”.³⁹

8. **Family:**

Nuclear family: “Married couple along with their dependent children who live in the same house”.⁴⁰

Joint family: “More than one married couple along with their dependent children who live in the same household. Male members are blood relatives and female members of the family are related by either marriage or blood”.⁴⁰

9. **Socio economic status**⁴¹:

Modified B. G. Prasad’s classification was used

Social Class		Original BG Prasad classification of 1961 (Rs. / month)	Modified BG Prasad classification for 2023 (Rs. / month)
I	Upper class	100 and above	8967 and above
II	Upper middle	50- 99	4484 - 8966
III	class	30- 49	2690 – 4483
IV	Middle class	15- 29	1345 – 2689
V	Lower middle	Below 15	Below 1345
	class		
	Lower class		

The BG Prasad Scale, established in 1961 with the Consumer Price Index (CPI) of 1960 as the reference point (indexed at 100), has undergone periodic updates. Over the years, adjustments and refinements have been necessary. To recalibrate the CPI to the 1960 baseline of 100, linkage factors were introduced in the years 1982, 2001, and 2016, with values of 4.63, 4.93, and 2.88, respectively

Average consumer price index for the year 2023 (1st January to 31st December)-
136.4

Correction factor = current index value (136.4) x linkage factor between 1960 and 1982 (4.63) x linkage factor between 1982 and 2001 (4.93) x linkage factor between 2001 and 2016 (2.88) whole divided by base index in 2016 (100) = 89.67

The new income values are calculated by using the formula, new income values = Correction factor x old income value of 1961.

10. Type of house:

Kacha – “The walls and/or roof of which are made of material other than those mentioned above, such as unburnt bricks, bamboos, mud, grass, reeds, thatch, loosely packed stones, etc. are treated as kutchra house”.⁴²

Semi pucca – “A house that has fixed walls made up of pucca material but roof is made up of the material other than those used for pucca house”.⁴²

Pucca – “A pucca house is one, which has walls and roof made of the following material. Wall material: Burnt bricks, stones (packed with lime or cement), cement concrete, timber, ekra etc”.⁴²

11. Overcrowding – “Is expressed as the number of persons divided by the

number of rooms. It is called overcrowding if these standards are exceeded”.⁴³

“Criteria for overcrowding – persons per room”

“1 room – 2 persons”

“2 rooms – 3 persons”

“3 rooms – 5 persons”

“4 rooms – 7 persons”

“5 or more rooms – 10 persons”

12. **Ventilated:** Natural ventilation was taken into consideration

Natural ventilation: “Natural forces (e.g. winds and thermal buoyancy force due to indoor and outdoor air density differences) drive outdoor air through purpose-built, building envelope openings. Purpose-built openings include windows, doors, solar chimneys, wind towers and trickle ventilators”.⁴⁴

13. **Tobacco use**⁴⁵: “For the assessment of history of use of tobacco in any form (smoking/smokeless) period of recall was considered for the past one year”.

Smoking tobacco:

Smokers: “Subjects those who had smoked in the past or smoking at present were considered as smokers”.⁴⁵

Non-Smokers: “Subjects who had never smoked any form of tobacco (Cigarettes/Beedi) were considered as non-smokers”.⁴⁵

14. **Alcohol consumption**⁴⁶: “For the assessment of alcohol consumption, period of recall

was considered for the past one year”.⁴⁶

Alcoholic: “A person who has been taking alcohol at least 30 ml per day for at least six

months preceding the survey”.⁴⁶

Non-Alcoholic: “Subject who had never consumed alcohol were considered and kept in the category of Non-Alcoholic”.⁴⁶

15. Body Mass Index (BMI) – According to the guidelines recommended by WHO, persons with BMI values of less than 18.5 were classified as “Underweight”, 18.5 to 24.9 were classified as “Normal weight”, 25 to 29.99 were classified as “over-weight” and 30 and above were classified as “Obese”.⁴³

Body Mass Index was calculated as;

$$\text{BMI} = \text{weight in kgs} / (\text{Height in Meter})^2$$

Classification BMI

Normal range 18.50-24.99

Overweight ≥ 25.00

Pre-obese 25.00-29.99

Obese class I 30.00-34.99

Obese class II 35.00-39.99

Obese class III ≥ 40.00

16. Sputum-positive - “A patient with two positive direct smear microscopy results or one positive direct smear microscopy result and one positive sputum culture for *Mycobacterium tuberculosis* (MTB) or one positive direct smear microscopy result and radiographic abnormalities consistent with active PTB as determined by a clinician”⁴⁷.

17. Sputum-negative – “A case of pulmonary tuberculosis (PTB) can be identified in a patient who has returned three sputum smear tests with negative results, yet presents with chest scans indicative of active PTB lesions, and exhibits at least one of the following criteria: (a) typical PTB symptoms such as coughing, spitting, and blood in sputum; (b) a markedly positive reaction to the purified protein derivative (PPD) test; (c) a favorable anti-MTB antibody test result; or (d) confirmation of TB lesions through histological analysis of tissues outside the lungs. Furthermore, a patient who shows a positive result for MTB in sputum culture, despite a negative sputum smear test, is also considered a PTB case.”⁴⁷

18. Definitions for outcomes of TB treatment⁴⁸:

Cured: “Microbiologically confirmed TB patients at the beginning of treatment who was smear or culture negative at the end of the complete treatment”.⁴⁸

Treatment Completed: “A TB patient who completed treatment without evidence of failure or clinical deterioration but with no record to show that the smear or culture results of biological specimen in the last month of treatment was negative, either because test was not done or because result is unavailable”.⁴⁸

Failure: “A TB patient whose biological specimen is positive by smear or culture at the end of treatment”.⁴⁸

Lost to follow up: “A patient whose treatment was interrupted for 1 consecutive month or more”.⁴⁸

Not evaluated: “A TB patient for whom no treatment outcome is assigned. This includes former Transfer out”.⁴⁸

Treatment regimen changed: “A TB patient who is on first line regimen and has been diagnosed as having DRTB and switched to drug resistant TB regimen prior to being declared as failed”.⁴⁸

Died: “A patient who has died during the course of anti TB treatment”.⁴⁸

Successful treatment outcome: “If TB patient was cured or completed treatment with resolution of symptoms”.⁴⁸

Unsuccessful treatment outcome: “If treatment of TB patients resulted in treatment failure, default or death & treatment regimen changed”.⁴⁸

19. Cartridge based nucleic acid amplification test (CBNAAT)⁴⁹:

Current gold standard for TB diagnosis. In addition, CBNAAT also provides information on drug susceptibility to rifampicin, which is a surrogate marker for identification of patients who are at risk to have MDR-TB, thus allowing the early initiation of standardized 2nd line TB treatment. Index patient of TB is the initially diagnosed person of any age with new or recurrent disease.

20. TB Household contact (HHC): “Family member or any other person living and sleeping in the same house and sharing same kitchen with pulmonary tuberculosis patient for at least three months before the commencement of treatment of tuberculosis.”⁵⁰

21. Definitions of Tuberculosis preventive treatment (TPT) outcomes⁶:

Treatment offered to individuals who are considered to be at risk of developing TB disease, in order to reduce that risk.

Following definitions from will be used for recording treatment outcomes of individuals treated with Tuberculosis Preventive Treatment.

Treatment completion: A person initiated on TPT who completed at least:

“80% (144/180) of recommended dose (Isoniazid) consumed within 133% of planned TPT duration (239 days). Completed includes treatment without interruption, temporary halting with subsequent continuation and completion”.⁶

Treatment failed: “A person initiated on TPT who developed active TB disease any time while on TPT course”.⁶

Died: “A person initiated on TPT who died for any reason while on TPT course”.⁶

Lost to follow-up: “TPT interrupted by person for eight consecutive weeks (2 months) or more”.⁶

TPT discontinuation due to toxicity: “A person whose TPT is permanently discontinued by the doctor due to adverse events or drug–drug interactions”.⁶

Not evaluated: “Such as records lost, transfer to another health facility without record of TPT completion”.⁶

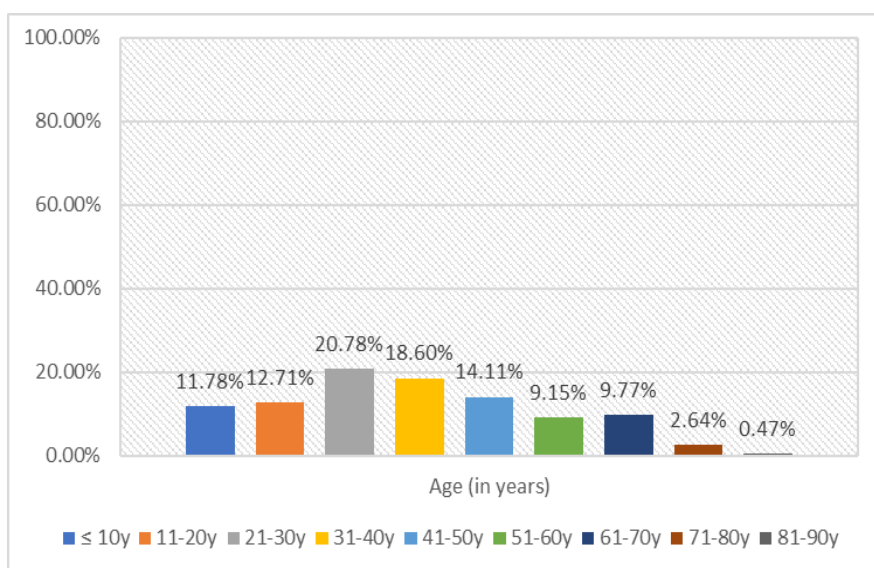
RESULTS

I. Socio- demographic profile of study participants (n= 645)

(Tuberculosis patients: 143, Household contacts: 502)

Table 1: Distribution of study participants according to Age

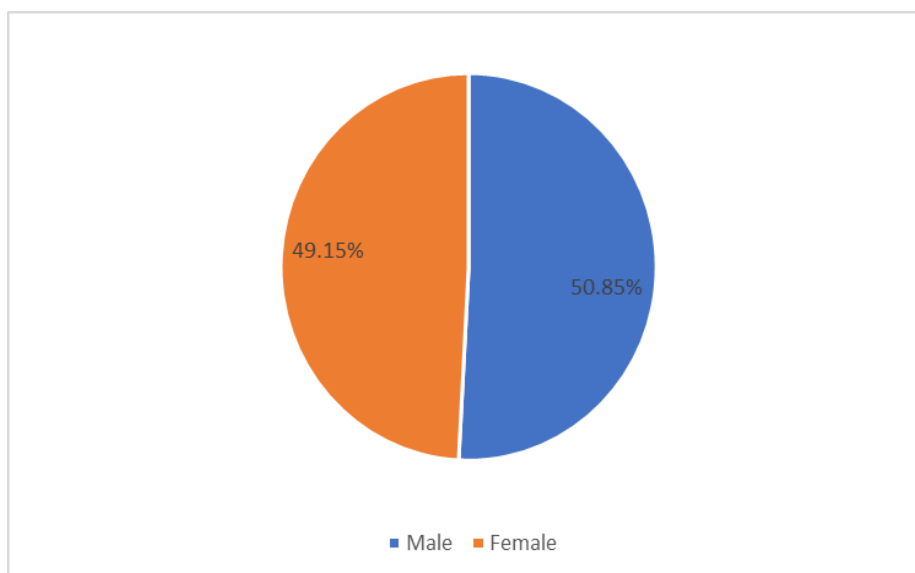
Age (in years)	Number	Percentage (%)
≤ 10	76	11.78
11-20	82	12.71
21-30	134	20.78
31-40	120	18.60
41-50	91	14.11
51-60	59	9.15
61-70	63	9.77
71-80	17	2.64
81-90	3	0.47
Total	645	100

Graph 1(Table 1): Distribution of study participants according to Age

In the present study, out of 645 study participants, 76 (11.78%) were aged 10 years or less, 82 (12.71%) were aged in between 11- 20 years, 134 (20.78%) were aged in between 21- 30 years, 120 (18.60%) were aged in between 31- 40 years, 91 (14.11%) were aged in between 41- 50 years, 59 (9.15%) were aged in between 51- 60 years, 63 (9.77%) were aged in between 61- 70 years, 17 (2.64%) were aged in between 71- 80 years and three (0.47%) were aged in between 81- 90 years. Mean age of the participants was 35.14 ± 18.76 years.

Table 2: Distribution of study participants according to Gender

Gender	Number	Percentage (%)
Male	328	50.85
Female	317	49.15
Total	645	100

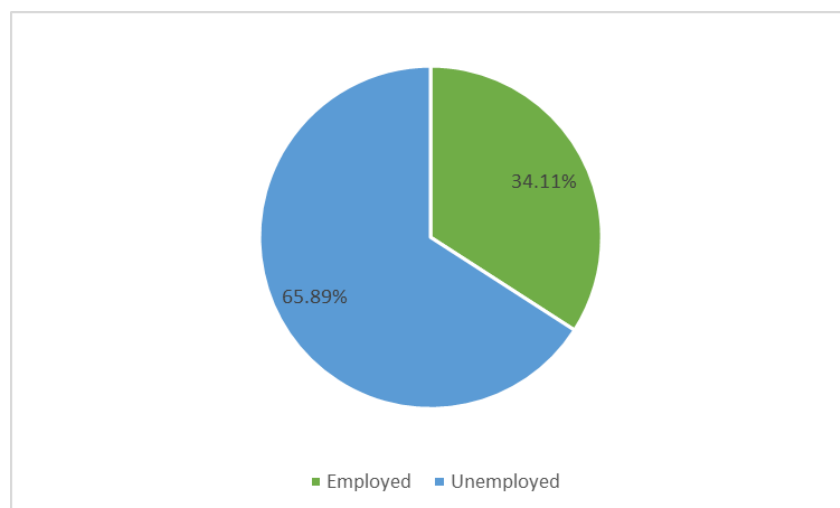
Graph 2 (Table 2): Distribution of study participants according to Gender

In the present study, out of 645 study participants, 328 (50.85%) were males and 317 (49.15%) were females

Table 3: Distribution of study participants according to Employment status

Employment status	Number	Percentage (%)
Employed	220	34.11
Unemployed	425	65.89
Total	645	100

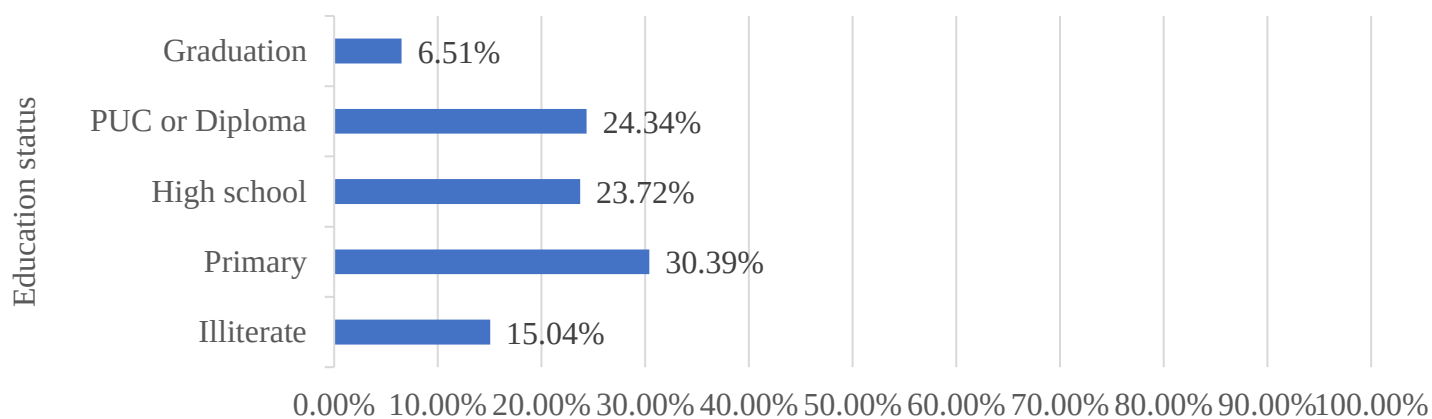
Graph 3 (Table 3): Distribution of study participants according to Employment status



In the present study, out of 645 study participants, 220 (34.11%) were employed and 425 (65.89%) were unemployed.

Table 4: Distribution of study participants according to Literacy status

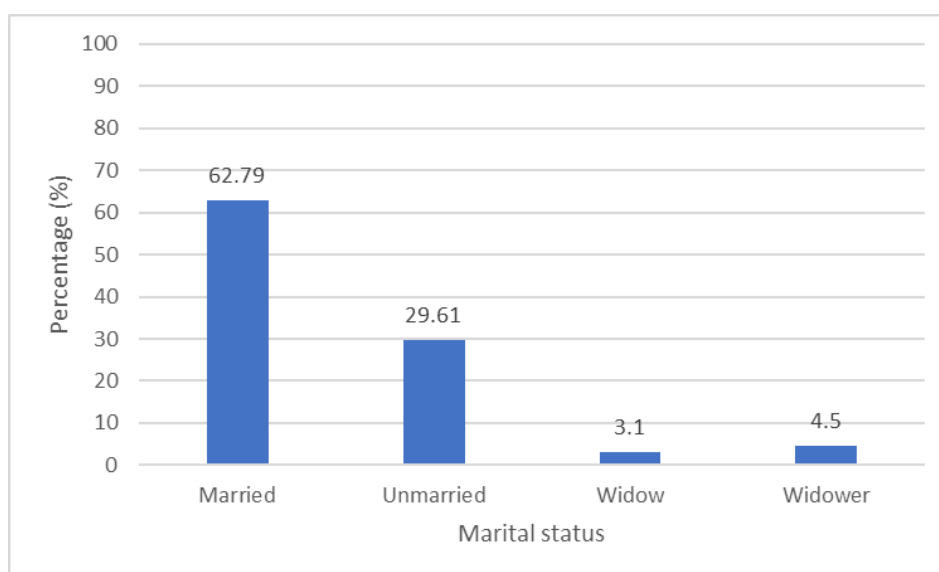
Literacy status	Number	Percentage (%)
Illiterate	97	15.04
Primary	196	30.39
High school	153	23.72
PUC or Diploma	157	24.34
Graduation	42	6.51
Total	645	100

Graph 4 (Table 4): Distribution of study participants according to literacy status

In the present study, out of 645 study participants, 196 (30.39%) had completed primary level education, 157 (24.34%) had completed pre university or diploma level education, 153 (23.72%) had completed high school level education, 97 (15.04%) were illiterates and 42 (6.51%) were graduates.

Table 5: Distribution of study participants according to Marital status

Marital status	Number	Percentage (%)
Married	405	62.79
Unmarried	191	29.61
Widow	20	3.10
Widower	29	4.50
Total	645	100

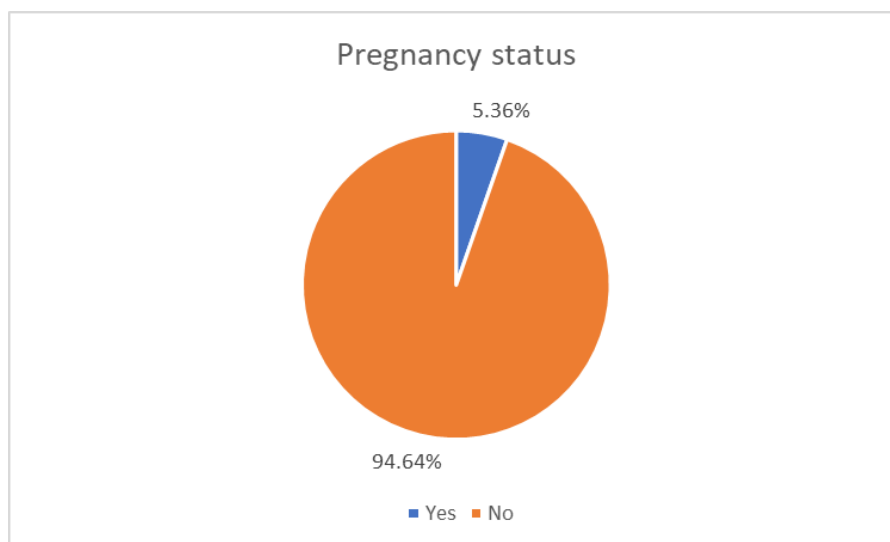
Graph 5 (Table 5): Distribution of study participants according to Marital status

In the present study, out of the 645 participants, 405 (62.79%) were married, 191 (29.61%) were unmarried, 29 (4.5%) were widowers and 20 (3.1%) were widows.

Table 6: Distribution of study participants according to Pregnancy status

(n= 317)

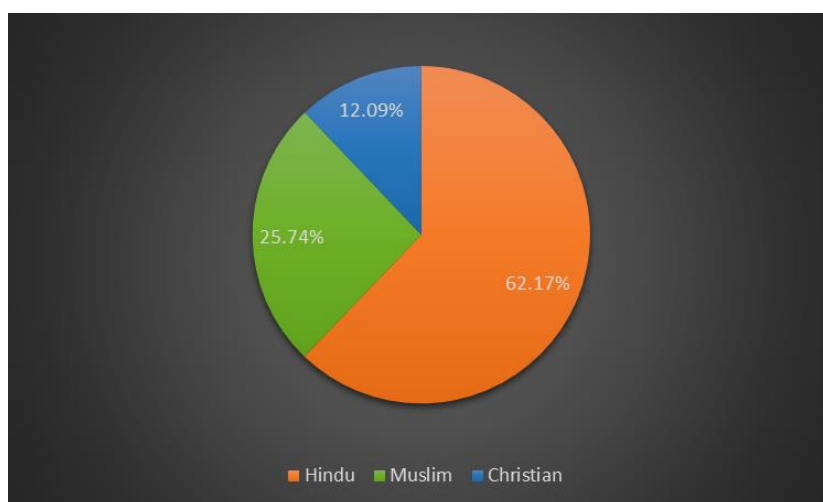
Pregnant	Number	Percentage (%)
Yes	17	5.36
No	300	94.64
Total	317	100

Graph 6 (Table 6): Distribution of study participants according to Pregnancy status

In the present study, out of 317 female study participants, 17 (5.36%) were pregnant and 300 (94.64%) were non pregnant.

Table 7: Distribution of study participants according to Religion

Religion	Number	Percentage (%)
Hindu	401	62.17
Muslim	166	25.74
Christian	78	12.09
Total	645	100

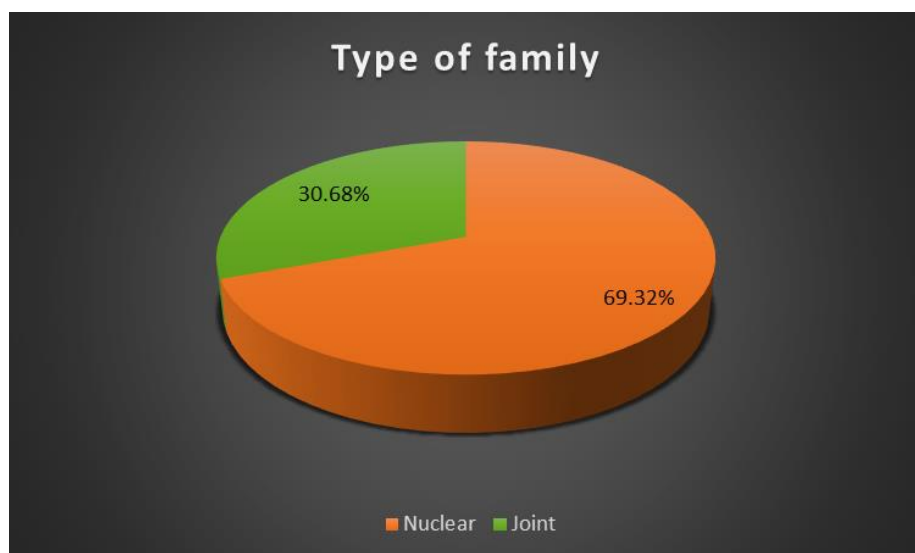
Graph 7 (Table 7): Distribution of study participants according to Religion

In the present study, out of 645 study participants, 401 (62.17%) were Hindus, 166 (25.74%) were Muslims and 78 (12.09%) were Christians.

Table 8: Distribution of study participants according to type of family

Type of family	Number	Percentage (%)
Nuclear	348	69.32
Joint	154	30.68
Total	645	100

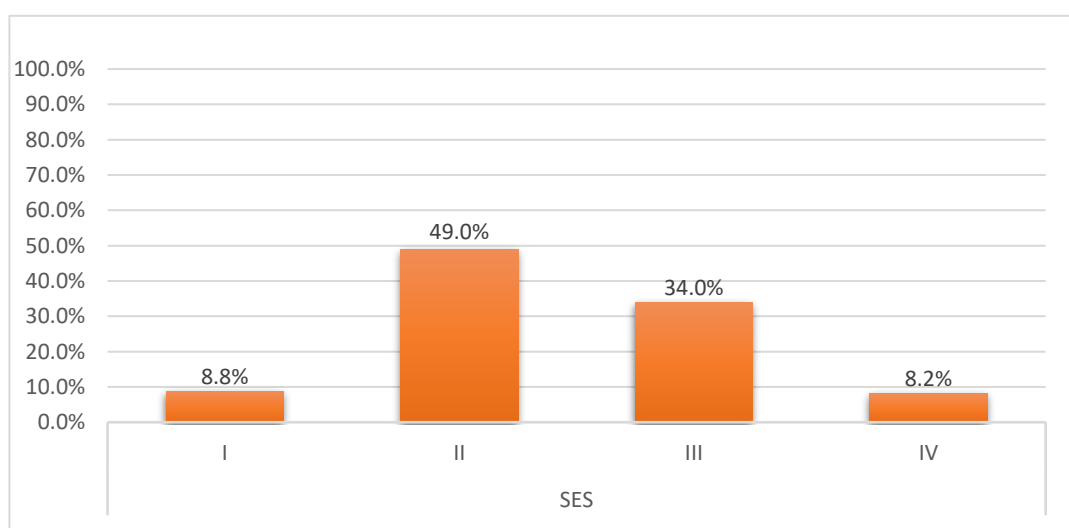
Graph 8 (Table 8): Distribution of study participants according to type of family



In the present study, out of 645 study participants, 348 (69.32%) belonged to nuclear families and 154 (30.68%) belonged to joint families.

Table 9: Distribution of study participants according to Socio Economic Status

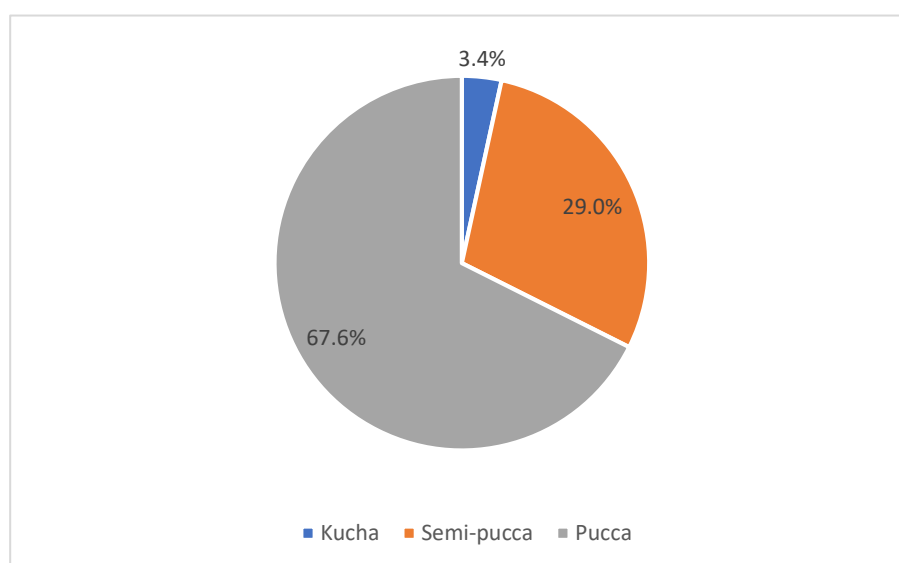
Socio economic status	Number	Percentage (%)
I	57	8.84
II	316	48.99
III	219	33.95
IV	53	8.22
Total	645	100

Graph 9 (Table 9): Distribution of study participants according to Socio Economic Status

In the current study, according to modified BG Prasad socio economic status classification, out of 645 study participants, 316 (48.99%) belonged to class II, 219 (33.95%) belonged to class III, 57 (8.84%) belonged to class I and 53 (8.22%) belonged to class IV.

Table 10: Distribution of study participants according to type of house

Type of house	Number	Percentage (%)
Kucha	22	3.41
Semi-pucca	187	28.99
Pucca	436	67.6
Total	645	100

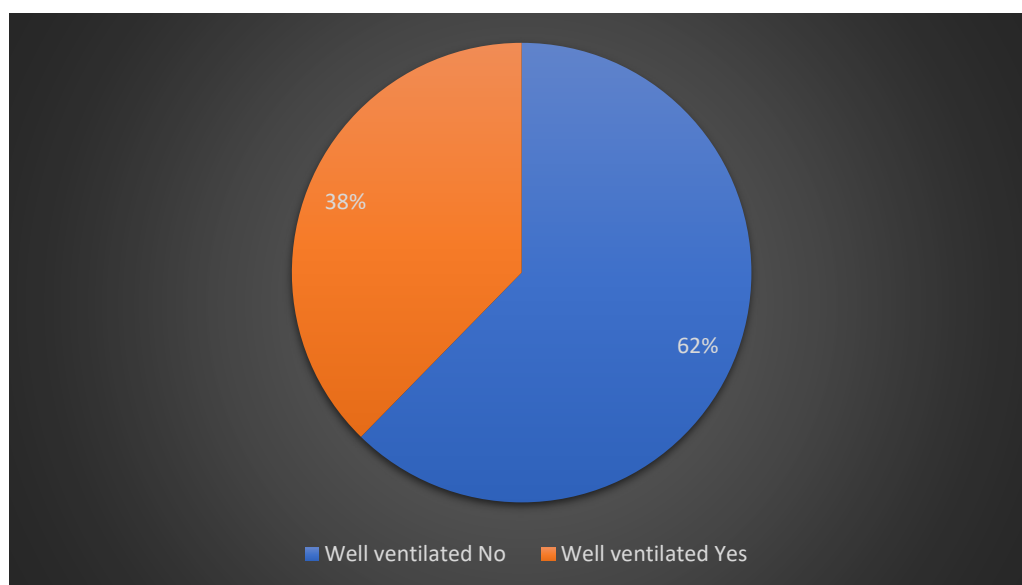
Graph 10 (Table 10): Distribution of study participants according to type of house

In the present study, out of 645 study participants, 436 (67.6%) were living in pucca houses, 187 (28.99%) were living in semi- pucca houses and 22 (3.41%) were living in kuccha houses.

Table 11: Distribution of study participants according to Ventilation of the House

Well ventilated	Number	Percentage (%)
Yes	243	37.67
No	402	62.33
Total	645	100

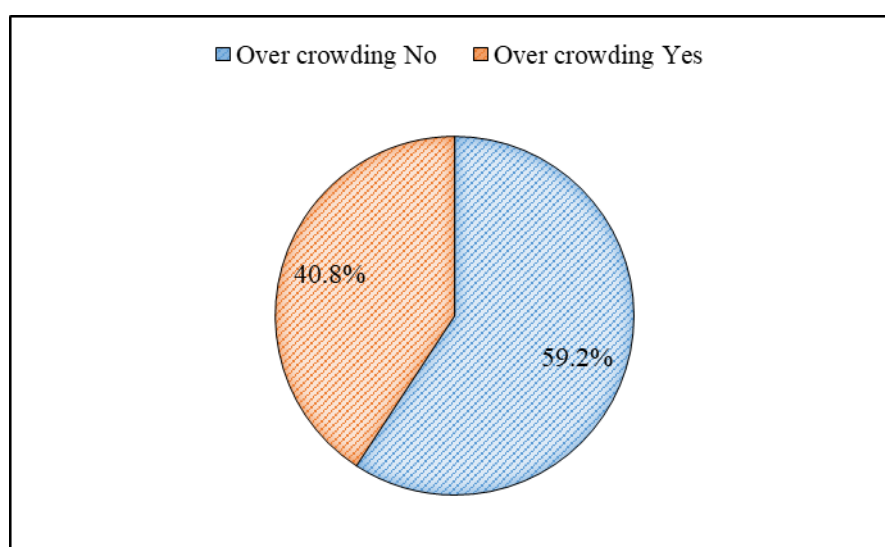
Graph 11 (Table 11): Distribution of study participants according to Ventilation of the House



In the present study, out of the 645 study participants, 243 (37.67%) were living in well-ventilated houses and 402 (62.33%) were not living in well-ventilated houses.

Table 12: Distribution of study participants according to Overcrowding

Overcrowding	Number	Percentage (%)
Yes	263	40.78
No	382	59.22
Total	645	100

Graph 12 (Table 12): Distribution of study participants according to Overcrowding

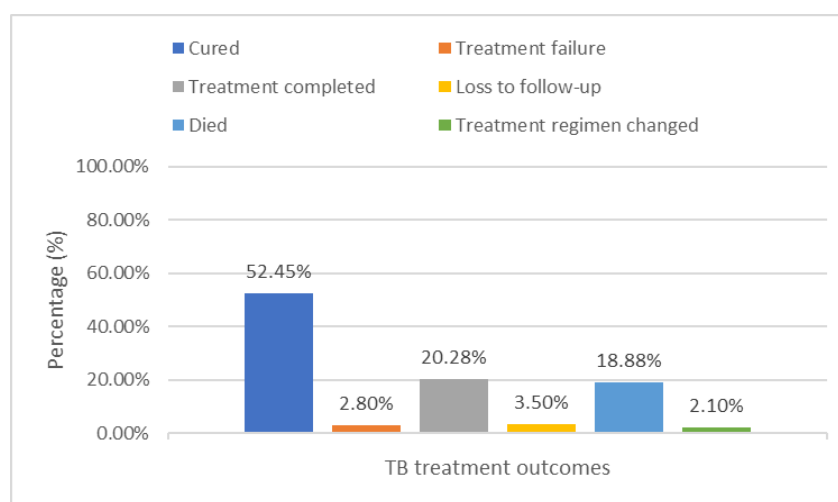
In the present study, out of the 645 study participants, 382 (59.22%) were living in the houses with no overcrowding and 263 (40.78%) were living in the houses with overcrowding.

II. Treatment outcome profile of study participants

Table 13: Distribution of Tuberculosis patients according to treatment outcomes
(n= 143)

Tuberculosis treatment outcomes	Number	Percentage (%)
Cured	75	52.45
Treatment failure	4	2.80
Treatment completed	29	20.28
Loss to follow-up	5	3.50
Died	27	18.88
Treatment regimen changed	3	2.10
Total	143	100

Graph 13 (Table 13): Distribution of Tuberculosis patients according to treatment outcomes



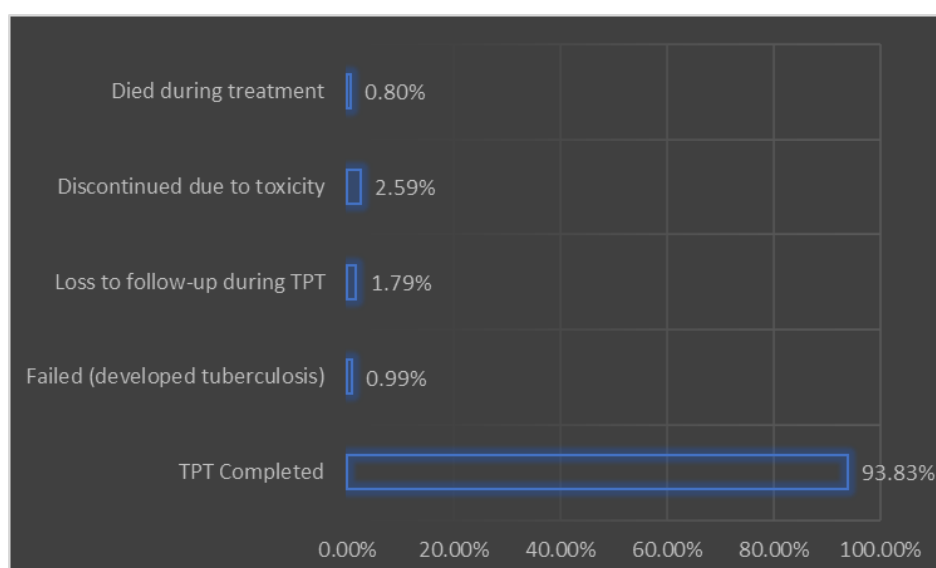
In the present study, out of 143 TB patients, 75 (52.45%) were cured patients, 29 (20.28%) were treatment completed patients, five (3.5%) were loss to follow-up patients, four (2.8%) were treatment failure patients, treatment regimen was changed in three (2.1%) patients and 27 (18.88%) patients had died during the TB treatment.

Table 14: Distribution of Household contacts according to Tuberculosis preventive treatment outcomes (n= 502)

TPT outcome	Number	Percentage (%)
TPT Completed	471	93.83
Failed (developed tuberculosis) *	5	0.99
Loss to follow-up during TPT	9	1.79
Discontinuation due to toxicity	13	2.59
Died during treatment	4	0.80
Total	502	100

*Out of 502 participants who were on TPT, 5 (0.99%) participants developed tuberculosis (Incidence of TB), indicating treatment failure.

Graph 14 (Table 14): Distribution of Household contacts according to Tuberculosis preventive treatment outcomes



In the current study, out of 502 household contacts who received TPT, 471 (93.83%) completed the treatment, 13 (2.59%) discontinued the treatment due to toxicity, nine (1.79%) were loss to follow-up participants, five (0.99%) participants developed tuberculosis indicating treatment failure and four (0.8%) participants died during the TPT treatment.

Out of Five participants who developed TB during the TPT treatment (TB incidence/ treatment failure), three participants were male, four participants were aged above 50 years and one participant was in the age group of 10- 20 years. Two participants were employed, three participants were illiterate, three participants were married. Three participants were Hindus and two participants were Muslims. Three participants were living in joint family with overcrowding and with no adequate ventilation. Three participants belonged to socio economic class II, one participant belonged to class I and one participant belonged to class IV. Four participants developed TB at the end of 6th month and one participant at the end of 4th month of TPT treatment

Table 15: Distribution of participants according to completion of Tuberculosis preventive treatment

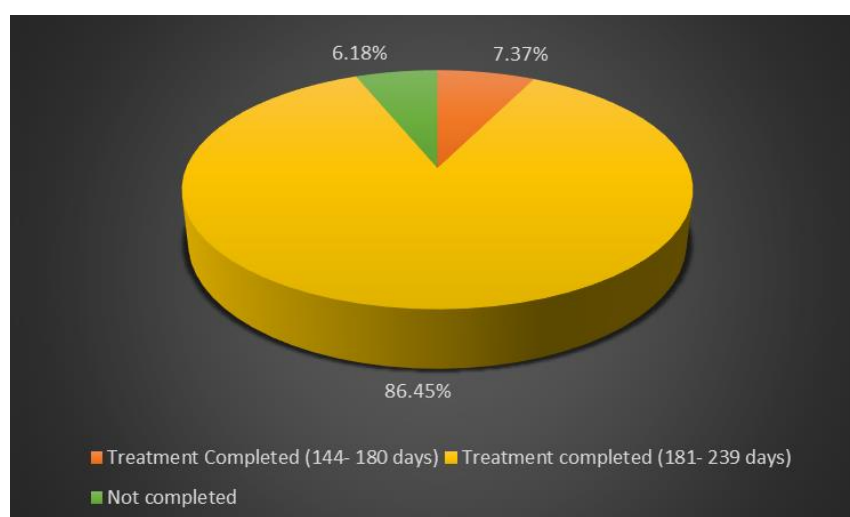
(n= 502)

Treatment status	Duration in days	Number	Percentage (%)
Treatment Completed*	144-180	37	7.37
	181-239	434	86.45
Not completed**		31	6.18
Total		502	100

*Treatment completed- at least 144 (80%) tablets with in the maximum duration of 239 (133%) days.

**Treatment not completed- treatment failed+ loss to follow-up+ Discontinuation due to toxicity+ Died

Graph 15 (Table 15): Distribution of participants according to completion of Tuberculosis preventive treatment



In the present study, out of 502 participants, 37 (7.37%) participants completed the treatment withing the duration of 144 to 180 days, 434 (86.45%) participants completed the treatment within the duration of 181 to 239 days and 31 (6.18%) participants did not complete the treatment.

III. Association between risk factors and Tuberculosis treatment outcomes. (n=143)

Table 16: Association between Age and Tuberculosis treatment outcomes

Age (in years)	Outcomes		Total
	Successful	Unsuccessful	
≤ 10	1 (50%)	1 (50%)	2 (100%)
11-20	8 (100%)	0 (0%)	8 (100%)
21-30	30 (93.75%)	2 (6.25%)	32 (100%)
31-40	22 (66.67%)	11 (33.33%)	33 (100%)
41-50	18 (75%)	6 (25%)	24 (100%)
51-60	16 (66.67%)	8 (33.33%)	24 (100%)
61-70	6 (42.86%)	8 (57.14%)	14 (100%)
71-80	3 (75%)	1 (25%)	4 (100%)
81-90	0 (0%)	2 (100%)	2 (100%)
Total	104 (72.73%)	39 (27.27%)	143 (100%)
$\chi^2 = 23.41$			df = 8
			p = 0.003498

In the current study, one (50%) out of two participants with less than or equal to 10 years age had successful outcomes. All the eight (100%) participants in the age group of 11- 20 years had successful outcomes. 30 (93.75%) out of 32, 22 (66.67%) out of 33, 18 (75%) out of 24, 16 (66.67%) out of 24, six (42.86%) out of 14 and three (75%) out of four participants in the age groups of 21-30, 31-40, 41-50, 51-60, 61-70 and 71-80 years respectively had successful outcomes. It was found that participants

who are less than or equal to 10 years old and greater than 60 years old had more unsuccessful outcomes. 11 to 60 years aged participants had more successful outcomes. This difference was found to be statistically significant. ($p= 0.003498$)

Table 17: Association between Gender and Tuberculosis treatment outcomes

Gender	Outcomes		Total
	Successful	Unsuccessful	
Male	53 (63.1%)	31 (36.9%)	84 (100%)
Female	51 (86.44%)	8 (13.56%)	59 (100%)
Total	104 (72.73%)	39 (27.27%)	143 (100%)
$\chi^2 = 9.523$			df = 1
			p = 0.00202

In the current study, out of 84 male participants, 53 (63.1%) had successful outcomes. Out of 59 female participants, 51 (86.44%) had successful outcomes. Females had more successful outcomes compared to males. This difference was found to be statistically significant. (p = 0.00202)

Table 18: Association between Literacy status and Tuberculosis treatment outcomes

Literacy status	Outcomes		Total
	Successful	Unsuccessful	
Illiterate	17 (56.67%)	13 (43.33%)	30 (100%)
Primary	20 (76.92%)	6 (23.08%)	26 (100%)
High school	25 (67.57%)	12 (32.43%)	37 (100%)
PUC or Diploma	34 (89.47%)	4 (10.53%)	38 (100%)
Graduation	8 (66.67%)	4 (33.33%)	12 (100%)
Total	104 (72.73%)	39 (27.27%)	143 (100%)
$\chi^2 = 10.224$			df = 4
			p = 0.02999 MC

Abbreviations: MC: Monte-Carlo's simulation used in the Chi-square test

In the present study, out of 30 illiterates, 17 (56.67%) had successful outcomes. Out of 26 participants with primary level education, 20 (76.92%) had successful outcomes. 25 (67.57%) out of 37, 34 (89.47%) out of 38, eight (66.67%) out of 12 participants with high school, pre university and graduate level education respectively had successful outcomes. Proportion of unsuccessful outcomes were more in illiterates compared to literates. This difference was found to be statistically significant. (p= 0.02999)

Table 19: Association between Marital status and Tuberculosis treatment outcomes

Marital status	Outcome		Total
	Successful	Unsuccessful	
Married	76 (71.03%)	31 (28.97%)	107 (100%)
Unmarried	18 (94.74%)	1 (5.26%)	19 (100%)
Widow	4 (80%)	1 (20%)	5 (100%)
Widower	6 (50%)	6 (50%)	12 (100%)
Total	104 (72.73%)	39 (27.27%)	143 (100%)
$\chi^2 = 8.0554$			df = 3
			p = 0.03798 MC

Abbreviations: MC: Monte-Carlo's simulation used in the Chi-square test

In the current study, 18 (94.74%) out of 19, four (80%) out of five, 76 (71.03%) out of 107 and six (50%) out of 12 participants under un married, widow, married and widower category respectively had successful outcomes. Married participants had more unsuccessful outcomes compared to unmarried/ single participants. This difference was found to be statistically significant. (p = 0.03798)

Table 20: Association between total treatment duration and Tuberculosis treatment outcomes

	Outcomes		Total
	Successful	Unsuccessful	
Total treatment duration in days	172.15±17.86	70.62±57.13	144.46±56.25
$\chi^2 = 3531.5$			$p = <0.0001$ MW

Abbreviations: MW: Mann-Whitney test.

In the current study, the mean total treatment duration among individuals with successful outcomes was 172.15±17.86 days, while for those with unsuccessful outcomes, it was 70.62±57.13 days. This difference was found to be statistically significant. ($p < 0.0001$)

Factors like area of residence, employment, pregnancy status, religion, type of family, socio economic status, type of house, ventilation of the house, overcrowding, type of TB, and treatment duration on the day of interview did not show any associations with Tuberculosis treatment outcomes. ($p > 0.05$)

IV. Association between risk factors and Tuberculosis preventive treatment

outcomes

(n= 502)

Table 21: Association between Age and Tuberculosis preventive treatment

outcomes

Age (in years)	Outcomes		Total
	Successful	Unsuccessful	
≤ 10	69 (93.24%)	5 (6.76%)	74 (100%)
11-20	74 (100%)	0 (0%)	74 (100%)
21-30	102 (100%)	0 (0%)	102 (100%)
31-40	85 (97.7%)	2 (2.3%)	87 (100%)
41-50	66 (98.51%)	1 (1.49%)	67 (100%)
51-60	28 (80%)	7 (20%)	35 (100%)
61-70	39 (79.59%)	10 (20.41%)	49 (100%)
71-80	8 (61.54%)	5 (38.46%)	13 (100%)
81-90	0 (0%)	1 (100%)	1 (100%)
Total	471 (93.82%)	31 (6.18%)	502 (100%)
$\chi^2 = 83.678$ $df = 8$ $p < 0.0001$ MC			

Abbreviations: MC: Monte-Carlo's simulation used in the Chi-square test

In the present study, 69 (93.24%) out of 74 participants aged ≤ 10 years had successful outcomes. All the 74 participants in the age group of 11- 20 years, 102 participants in the age group of 21- 30 years had successful outcomes. 85 (97.7%) out of 87, 66 (98.51%) out of 67, 28 (80%) out of 35, 39 (79.59%) out of 49, and Eight (61.54%) out of 13 participants in the age groups of 31-40, 41-50, 51-60, 61-70, and 71-80 years respectively had successful outcomes. One and only participant in the age group of 81-90 years had unsuccessful outcomes. Unsuccessful outcomes were more among the participants aged greater than 50 years compared to the participants aged less than 50 years. This difference was found to be statistically significant ($p < 0.0001$)

Table 22: Association between Employment status and Tuberculosis preventive treatment outcomes

Employment status	Outcomes		Total
	Successful	Unsuccessful	
Employed	151 (99.34%)	1 (0.66%)	152 (100%)
Unemployed	320 (91.43%)	30 (8.57%)	350 (100%)
Total	471 (93.82%)	31 (6.18%)	502 (100%)
$\chi^2 = 11.454$			df = 1
			p = 0.00071

In the present study, 151 (99.34%) out of 152 employed participants and 320 (91.43%) out of 350 unemployed participants had successful outcomes. More successful outcomes were seen among employed participants compared to unemployed participants. This difference was found to be statistically significant. (p = 0.00071)

Table 23: Association between Literacy status and Tuberculosis preventive treatment outcomes

Literacy status	Outcomes		Total
	Successful	Unsuccessful	
Illiterate	55 (82.09%)	12 (17.91%)	67 (100%)
Primary	153 (90%)	17 (10%)	170 (100%)
High school	115 (99.14%)	1 (0.86%)	116 (100%)
PUC or Diploma	118 (99.16%)	1 (0.84%)	119 (100%)
Graduation	30 (100%)	0 (0%)	30 (100%)
Total	471 (93.82%)	31 (6.18%)	502 (100%)
$\chi^2 = 33.698$			df = 4
			p = 0.0004998 MC

Abbreviations: MC: Monte-Carlo's simulation used in the Chi-square test

In the present study, out of 67 participants, 55 (82.09%) participants with no formal education had successful outcomes. Out of 170 participants with primary level education, 153 (90%) had successful outcomes. Out of 116 participants, 115 (99.14%) participants with high school level education, out of 119 participants, 118 (99.16%) with pre-university or diploma level education had successful outcomes. All the 30 (100%) participants who completed their graduation had successful outcomes. Unsuccessful outcomes were more among illiterates compared to literates. This difference was found to be statistically significant. (p = 0.0004998)

Table 24: Association between Religion and Tuberculosis preventive treatment outcomes

Religion	Outcomes		Total
	Successful	Unsuccessful	
Hindu	293 (94.82%)	16 (5.18%)	309 (100%)
Muslim	126 (96.18%)	5 (3.82%)	131 (100%)
Christian	52 (83.87%)	10 (16.13%)	62 (100%)
Total	471 (93.82%)	31 (6.18%)	502 (100%)
$\chi^2 = 12.39$			df = 2
			p = 0.00299 MC

Abbreviations: MC: Monte-Carlo's simulation used in the Chi-square test

In the present study, out of 309 Hindu participants, 293 (94.82%) had successful outcomes. Out of 131 Muslim participants, 126 (96.18%) had successful outcomes. Out of 62 Christian participants, 58 (93.55%) had successful outcomes. More unsuccessful outcomes were seen among Christians compared to Hindus and Muslims. This difference was found to be statistically significant. (p = 0.00299)

Table 25: Association between Relation with Index case and Tuberculosis preventive treatment outcomes

Relation with index case	Outcome		Total
	Successful	Unsuccessful	
Partner	105 (95.45%)	5 (4.55%)	110 (100%)
Offspring	153 (96.84%)	5 (3.16%)	158 (100%)
Sibling	26 (92.86%)	2 (7.14%)	28 (100%)
Parent	69 (85.19%)	12 (14.81%)	81 (100%)
Others	118 (94.4%)	7 (5.6%)	125 (100%)
Total	471 (93.82%)	31 (6.18%)	502 (100%)
$\chi^2 = 13.528$			df = 4
			p = 0.01199 MC

Abbreviations: MC: Monte-Carlo's simulation used in the Chi-square test

In the present study, out of 110 participants who are partners to the index TB cases, 105 (95.45%) had successful outcomes. Out of 158 offsprings, 28 siblings, 81 parents and 125 others who are related to index cases, 153 (96.84%), 26 (92.86%), 69 (85.19%) and 118 (94.4%) respectively had successful outcomes. More unsuccessful outcomes were seen among the parents of index case compared to the participants with other relations to index case. This difference was found to be statistically significant. (p = 0.01199)

Table 26: Association between symptoms and Tuberculosis preventive treatment outcomes

Symptoms	Outcomes		Total
	Successful	Unsuccessful	
None	441 (96.71%)	15 (3.29%)	456 (100%)
Cough < 2 weeks	17 (73.91%)	6 (26.09%)	23 (100%)
Cough > 2 weeks	5 (62.5%)	3 (37.5%)	8 (100%)
Fever < 2 weeks	5 (62.5%)	3 (37.5%)	8 (100%)
Fever > 2 weeks	2 (66.67%)	1 (33.33%)	3 (100%)
Generalized weakness	1 (100%)	0 (0%)	1 (100%)
Cough+ fever < 2 weeks	0 (0%)	3 (100%)	3 (100%)
Total	471 (93.82%)	31 (6.18%)	502 (100%)
$\chi^2 = 98.855$			df = 6
			p = 0.0004998 MC

Abbreviations: MC: Monte-Carlo's simulation used in the Chi-square test

In the present study, successful outcomes were seen in 441 (96.71%) out of 456 participants with no symptoms. 17 (73.91%) out of 23 participants with cough lasting less than 2 weeks, five (62.5%) out of eight participants with a cough lasting more than 2 weeks, five (62.5%) out of eight participants with a fever lasting less than 2 weeks and two (66.67%) out of three participants with a fever lasting more than 2 weeks had successful outcomes. One and only participant with generalized weakness

had successful outcome. All the three participants with both cough and fever for less than 2 weeks had unsuccessful outcomes. More unsuccessful outcomes were seen among the participants with symptoms of cough and/ or fever compared to the participants with no symptoms. This difference was found to be statistically significant. ($p = 0.0004998$)

Table 27: Association between comorbidities and Tuberculosis preventive treatment outcomes

Comorbidities	Outcome		Total
	Successful	Unsuccessful	
None	370 (98.14%)	7 (1.86%)	377 (100%)
Hypertension	15 (100%)	0 (0%)	15 (100%)
Diabetes	11 (100%)	0 (0%)	11 (100%)
Hypertension+ Diabetes mellitus	65 (79.27%)	17 (20.73%)	82 (100%)
Asthma	10 (58.82%)	7 (41.18%)	17 (100%)
Total	471 (93.82%)	31 (6.18%)	502 (100%)
$\chi^2 = 79.779$ $df = 4$ $p = 0.0004998$ MC			

Abbreviations: MC: Monte-Carlo's simulation used in the Chi-square test

In the present study, successful outcomes were seen in 370 (98.14%) out of 377 participants with no history of comorbidities. 65 (79.27%) out of 82 participants with both hypertension and diabetes had successful outcomes. 10 (58.82%) out of 17 participants with Asthma had successful outcomes. All the 15 and 11 participants with hypertension and diabetes respectively had successful outcomes. Unsuccessful outcomes were seen more among the participants having both hypertension and diabetes as well as asthma compared to the participants with no comorbidities and hypertension or diabetes alone. This difference was found to be statistically significant. ($p = 0.0004998$).

Table 28: Association between history of medication for other diseases and Tuberculosis preventive treatment outcomes

Medication	Outcomes		Total
	Successful	Unsuccessful	
None	371 (97.89%)	8 (2.11%)	379 (100%)
Anti- hypertensive	16 (100%)	0 (0%)	16 (100%)
Anti-diabetic	10 (100%)	0 (0%)	10 (100%)
Anti-hypertensive and anti-diabetic	74 (76.29%)	23 (23.71%)	97 (100%)
Total	471 (93.82%)	31 (6.18%)	502 (100%)
$\chi^2 = 64$ df = 3 p = 0.0004998 MC			

Abbreviations: MC: Monte-Carlo's simulation used in the Chi-square test

In the current study, out of 379 participants who are not on any other medications, 371 (97.89%) participants had successful outcomes. 74 (76.29%) out of 97 participants who are on both anti-hypertensive and anti-diabetic medications had successful outcomes. All the 16 and 10 participants who are on Anti- hypertensive and Anti- diabetic medication had successful outcomes. Participants who are on both anti-hypertensive and anti-diabetic drugs had more unsuccessful outcomes compared to the participants who are not on any medication and on anti-hypertensive or anti-diabetic drugs alone. This difference was found to be statistically significant. (p = 0.0004998)

Table 29: Association between presence of BCG scar and Tuberculosis preventive treatments outcomes

BCG scar	Outcomes		Total
	Successful	Unsuccessful	
present	468 (94.35%)	28 (5.65%)	496 (100%)
uncertain	3 (50%)	3 (50%)	6 (100%)
Total	471 (93.82%)	31 (6.18%)	502 (100%)
$\chi^2 = 20.13$			df = 1
			p = 0.0004998 MC

Abbreviations: MC: Monte-Carlo's simulation used in the Chi-square test

In the present study, 468 (94.35%) out of 496 participants with BCG scar had successful outcomes. three (50%) out of six participants with uncertain scar status had successful outcomes. Participants with BCG scar had better outcomes compared to the participants with uncertain BCG scar status. This difference was found to be statistically significant. (p = 0.0004998)

Table 30: Association between cigarette smoking and Tuberculosis preventive treatment outcomes

	Outcomes		Total
	Successful	Unsuccessful	
Duration of cigarette Smoking (years)	1.39±5.28	7.74±11.77	1.78±6.07
$\chi^2 = 5388$			$p < 0.0001$ MW

Abbreviations: MW: Mann-Whitney test.

In the present study, the mean duration of cigarette smoking among individuals with successful outcomes was 1.39 ± 5.28 years, while for those with unsuccessful outcomes, it was 7.74 ± 11.77 years. Duration of cigarette smoking was more among the participants with unsuccessful outcomes. This difference was found to be statistically significant. ($p < 0.0001$)

Table 31: Association between alcohol consumption and Tuberculosis preventive treatment outcomes

	Outcomes		Total
	Successful	Unsuccessful	
Duration of Alcohol consumption (years)	1.24±4.85	6.68±10.89	1.58±5.56
$\chi^2 = 5605$			$p < 0.0001$ MW

Abbreviations: MW: Mann-Whitney test.

In the present study, the mean duration of alcohol consumption among individuals with successful and unsuccessful outcomes was 1.24 ± 4.85 years and 6.68 ± 10.89 years respectively. Duration of alcohol consumption was more among the participants with unsuccessful outcomes. This difference was found to be statistically significant. ($p < 0.0001$)

Table 32: Association between chewing tobacco and Tuberculosis preventive treatment outcomes

	Outcomes		Total
	Successful	Unsuccessful	
Duration of Chewing tobacco (years)	0.7±3.52	6.26±10.7	1.05±4.5
$\chi^2 = 5448.5$			$p < 0.0001$ MW

Abbreviations: MW: Mann-Whitney test.

In the present study, the mean duration of chewing tobacco among participants with successful outcomes was 0.7 ± 3.52 years, while among those with unsuccessful outcomes, it was 6.26 ± 10.7 years. Duration of chewing tobacco was more among the participants with unsuccessful outcomes. This difference was found to be statistically significant. ($p < 0.0001$).

Table 33: Association between duration between Index case diagnosis and tuberculosis preventive treatment initiation in the Household contacts and Tuberculosis preventive treatment outcomes.

	Outcome		Total
	Successful	Unsuccessful	
Duration between Index case diagnosis and TPT initiation in the HHC (days)	16.97±2.43	18.23±1.98	17.05±2.43
$\chi^2 = 5152.5$			p= 0.005051 MW

Abbreviations: MW: Mann-Whitney test.

In the present study, the mean duration between the index case diagnosis and the initiation of TPT among HHC was 16.97 ± 2.43 days for participants with successful outcomes and 18.23 ± 1.98 days for those with unsuccessful outcomes. Duration between the Index case diagnosis and TPT initiation was less among the participants with successful outcomes This difference was found to be statistically significant. (p= 0.005051)

Table 34: Association between counselling regarding side effects of Tuberculosis preventive treatment and tuberculosis preventive treatment outcomes

Counselling regarding side effects of the TPT	Outcomes		Total
	Successful	Unsuccessful	
Done	471 (94.2%)	29 (5.8%)	500 (100%)
Not done	0 (0%)	2 (100%)	2 (100%)
Total	471 (93.82%)	31 (6.18%)	502 (100%)
$\chi^2 = 30.509$ $df = 1$ $p = 0.003498$ MC			

Abbreviations: MC: Monte-Carlo's simulation used in the Chi-square test

In the current study, out of 500 participants who received counselling about the side effects of the Tuberculosis Preventive Treatment (TPT) regimen, 471 (94.2%) had successful outcomes. Both the participants who had not undergone the counselling had unsuccessful outcomes. Participants who did not receive the counselling had more unsuccessful outcomes compared to the participants who received the counselling. This difference was found to be statistically significant. ($p = 0.003498$).

Table 35: Association between Body Mass Index (BMI) and Tuberculosis preventive treatment outcomes

	Outcomes		Total
	Successful	Unsuccessful	
BMI (kg/m²)	23.87±3.4	22.58±3.19	23.79±3.4
$\chi^2 = 9434$			p= 0.00638 MW

Abbreviations: MW: Mann-Whitney test.

In the present study, the mean Body Mass Index (BMI) of participants with successful outcomes was 23.87 ± 3.4 kg/m², while for those with unsuccessful outcomes, it was 22.58 ± 3.19 kg/m². BMI was high among the participants with successful outcomes. This difference was found to be statistically significant. (p= 0.00638)

Table 36: Association between Duration of follow-up and Tuberculosis preventive treatment outcomes

	Outcomes		Total
	Successful	Unsuccessful	
Duration of follow-up (in months)	15.9±1.6	14.19±3.54	15.79±1.82
$\chi^2 = 9326.5$			p= 0.008441 MW

Abbreviations: MW: Mann-Whitney test.

In the present study, the mean duration of follow-up for participants with successful and unsuccessful treatment outcomes was 15.9 ± 1.6 months and 14.19 ± 3.54 months respectively. Duration of follow-up was more among the participants with successful outcomes. This difference was found to be statistically significant. (p= 0.008441)

Table 37: Association between total tablets consumed and Tuberculosis preventive treatment outcomes

	Outcomes		Total
	Successful	Unsuccessful	
Total tablets consumed	166.03±7.72	121.71±22.57	163.29±14.16
$\chi^2 = 14553$			$p < 0.0001$ MW

Abbreviations: MW: Mann-Whitney test.

In the current study, out of total 180 tablets to be consumed, the mean number of total tablets consumed by participants with successful outcomes was 166.03 ± 7.72 tablets, while those with unsuccessful outcomes, it was 121.71 ± 22.57 tablets. This difference was found to be statistically significant. ($p < 0.0001$)

Table 38: Association between number of discontinuation periods and Tuberculosis preventive treatment outcomes

	Outcomes		Total
	Successful	Unsuccessful	
Number of discontinuation periods	4.14±1.47	7.48±1.77	4.34±1.69
$\chi^2 = 1152$			p< 0.0001 MW

Abbreviations: MW: Mann-Whitney test.

In the current study, the mean number of discontinuation periods in participants with successful outcomes was 4.14 ± 1.47 , while for those with unsuccessful outcomes, it was 7.48 ± 1.77 . Number of discontinuation periods were more among the participants with unsuccessful outcomes. This difference was found to be statistically significant. (p< 0.0001)

Table 39: Association between duration of treatment discontinuation and Tuberculosis preventive treatment outcomes

	Outcomes		Total
	Successful	Unsuccessful	
Duration of treatment discontinuation (in days)	23.73±10.9	53.97±20.06	25.59±13.73
$\chi^2 = 1218.5$			$p < 0.0001$ MW

Abbreviations: MW: Mann-Whitney test.

In the present study, the mean duration of treatment discontinuation among participants with successful and unsuccessful outcomes was 23.73 ± 10.9 days and 53.97 ± 20.06 days respectively. Duration of treatment discontinuation was more among the participants with unsuccessful outcomes. This difference was found to be statistically significant. ($p < 0.0001$)

Table 40: Association between reasons for discontinuation of Tuberculosis preventive treatment and treatment outcomes

Reasons for discontinuation of TPT	Outcomes		Total
	Successful	Unsuccessful	
Developed GI symptoms (Nausea, vomiting, abdominal discomfort)	42 (77.78%)	12 (22.22%)	54 (100%)
Developed cough	2 (66.67%)	1 (33.33%)	3 (100%)
Developed fever	1 (100%)	0 (0%)	1 (100%)
Developed loss of appetite	3 (100%)	0 (0%)	3 (100%)
No symptoms of TB during the prophylaxis period	7 (100%)	0 (0%)	7 (100%)
Longer duration of treatment	171 (96.61%)	6 (3.39%)	177 (100%)
No family support	5 (50%)	5 (50%)	10 (100%)
Workload	103 (100%)	0 (0%)	103 (100%)
Forgot to take	134 (98.53%)	2 (1.47%)	136 (100%)
Developed both fever and cough	3 (37.5%)	5 (62.5%)	8 (100%)
Total	471 (93.82%)	31 (6.18%)	502 (100%)
$\chi^2 = 119.84$ df = 9 p = 0.0004998 MC			

Abbreviations: MC: Monte-Carlo's simulation used in the Chi-square test

In the present study, out of 54 participants who developed GI symptoms, 12 (22.22%) had unsuccessful outcomes. Out of three participants who developed cough alone, one (33.33%) participant had unsuccessful outcomes. Out of 177 participants who said that long duration of treatment as the reason for discontinuation of the treatment, six (3.39%) had unsuccessful outcomes. 5 (50%) out of 10, two (1.47%) out of 136 and five (62.5%) out of eight participants who do not have family support, who forgot to take medication and who developed both fever as well as cough respectively had unsuccessful outcomes. Unsuccessful outcomes were seen more among the participants who developed GI symptoms, cough alone, both fever and cough, in the participants who felt that the treatment duration was long, who don't have family support and who forgot to take the medication. This difference was found to be statistically significant. ($p = 0.0004998$).

Factors like Gender, marital status, pregnancy status, type of family, socio economic status, type of house, ventilation of the house, overcrowding, sleep location and total treatment duration did not show any association with successful treatment outcomes. ($p > 0.05$)

Table 41: Univariate logistic regression analysis of the factors associated with successful Tuberculosis treatment outcomes

Risk factors		UOR (95% CI)	p-value
Gender	Female	1	
	Male	0.2682 (0.1063, 0.6137)	0.00293
Literacy status	Illiterate	1	-
	Graduation	1.5294 (0.3889, 6.7705)	0.5521
	High school	1.5931 (0.5881, 4.3781)	0.3602
	Primary	2.5490 (0.8199, 8.6329)	0.1149
	PUC or Diploma	6.5 (1.9707, 25.9362)	0.00367
Total treatment duration (6 months)		1.0584 (1.0391, 1.0925)	<0.0001

Abbreviations: UOR: Unadjusted Odds Ratio; CI: Confidence Interval

In the current study, univariate logistic regression analysis indicated that the gender, literacy status, and the total duration of treatment were the risk factors and effects the tuberculosis treatment outcomes.

Male participants were 0.2682 times less likely to have successful outcomes compared to female participants [UOR: 0.2682; 95% CI (0.1063, 0.6137); $p=0.00293$]. Although not statistically significant, participants who had completed

graduation were 1.53 times more likely to have successful outcomes compared to illiterates [UOR: 1.5294; 95% CI: (0.3889, 6.7705); $p=0.5521$]. Those who completed high school level education were 1.59 times more likely to have successful outcomes compared to illiterates [UOR: 1.5931; 95% CI: (0.5881, 4.3781); $p=0.3602$]. Participants with primary level education were 2.55 times more likely to have successful outcomes compared to illiterates [UOR: 2.5490; 95% CI: (0.8199, 8.6329)], though this was not statistically significant ($p=0.1149$). Individuals who completed their pre-university level education were 6.5 times more likely to have successful outcomes when compared to illiterates [UOR: 6.5; 95% CI: (1.9707, 25.9362)], and this was statistically significant ($p=0.00367$). Participants who completed 6 months of tuberculosis treatment were 1.058 times more likely to have successful outcomes [UOR: 1.0584; 95% CI (1.0391, 1.0925); $p<0.0001$]

Table 42: Multiple logistic regression analysis of the factors associated with successful tuberculosis treatment outcomes

Risk factors		AOR (95% CI)	p-value
Gender	Female	1	
	Male	0.2902 (0.0457, 1.3799)	0.1415
Literacy status	Illiterate	1	-
	Graduation	0.0431 (0.0016, 0.5298)	0.0262
	High school	0.2328 (0.0113, 2.3379)	0.2623
	Primary	2.1615 (0.065, 148.1743)	0.671
	PUC or Diploma	0.8491 (0.0344, 15.8056)	0.9109
Total treatment duration (6 months)		1.0651 (1.0432, 1.1028)	<0.0001

Abbreviations: AOR: Adjusted Odds Ratio; CI: Confidence Interval

In the present study, multivariate logistic regression analysis demonstrated that tuberculosis treatment outcomes were influenced by literacy status and total treatment duration.

Male participants were 0.29 times less likely to have successful outcomes compared to female patients [AOR: 0.2902; 95% CI (0.0457, 1.3799); $p = 0.1415$]. Patients who had completed their graduation were 0.04 times less likely to have successful outcomes compared to illiterates [AOR: 0.0431; 95% CI: (0.0016,

0.5298)], and this was statistically significant ($p=0.0262$). Those who had completed high school education were 0.23 times less likely to have successful outcomes compared to illiterates [AOR: 0.2328; 95% CI: (0.0113, 2.3379); $p=0.2623$]. Patients who had completed primary level education were 2.16 times more likely to have successful outcomes compared to illiterate individuals [AOR: 2.1615; 95% CI: (0.065, 148.1743); $p=0.671$]. Patients who had completed pre-university level education were 0.85 times less likely to have successful outcomes when compared to illiterates [AOR: 0.8491; 95% CI: (0.0344, 15.8056); 0.9109]. Participants who completed 6 months of tuberculosis treatment were 1.065 times more likely to have successful outcomes [AOR: 1.0651; 95% CI (1.0432, 1.1028); $p<0.0001$]

Table 43: Univariate logistic regression analysis of the factors associated with successful Tuberculosis preventive treatment outcomes

Risk factors		UOR (95% CI)	p-value
Gender	Female	1	-
	Male	0.8796 (0.4205, 1.8305)	0.7303
BMI		1.1042 (1.0014, 1.2119)	0.0407
Total tablets consumed (144- 180) *		1.4191 (1.3235, 1.5583)	<0.0001
Number of treatment discontinuation periods		0.33346 (0.2017, 0.4908)	<0.0001

Abbreviations: UOR: Unadjusted Odds Ratio; CI: Confidence Interval

*144 tablets- 80% of treatment; 180 tablets- 100% of treatment.

In the current study, univariate logistic regression analysis indicated that tuberculosis preventive treatment outcomes were influenced by BMI, total number of tablets consumed, and the number of discontinuation periods.

Male participants were 0.88 times less likely to have successful TPT outcomes compared to female participants [UOR: 0.8796; 95% CI (0.4205, 1.8305); $p = 0.7303$]. With increase in BMI, the participants had 1.1042 times chances of having successful outcomes [UOR: 1.1042; 95% CI (1.0014, 1.2119); $p = 0.0407$]. Participants who completed $\geq 80\%$ of the treatment were 1.4191 times more likely to have successful outcomes [UOR: 1.4191; 95% CI (1.3235, 1.5583); $p < 0.0001$]. With increase in number of treatment discontinuation periods, the participants had 0.33 times less likely chances of having successful outcomes [UOR: 0.33346; 95% CI (0.2017, 0.4908); $p < 0.0001$].

Table 44: Multiple logistic regression analysis of factors associated with successful Tuberculosis Preventive Treatment outcomes

Risk factors		AOR (95% CI)	p-value
Gender	Female	1	-
	Male	0.2391 (0.0957, 0.5409)	0.0012
BMI		1.1546 (1.0172, 1.3354)	<0.0001
Total tablets consumed (144- 180) *		1.4278 (1.3666, 1.5036)	<0.0001
Number of discontinuation periods		0.5108 (0.4084, 0.6256)	<0.0001

Abbreviations: AOR: Adjusted Odds Ratio; CI: Confidence Interval

*144 tablets- 80% of treatment; 180 tablets- 100% of treatment.

In the current study, multivariate logistic regression analysis revealed that tuberculosis preventive treatment outcomes were influenced by gender, BMI, number of tablets consumed, and the number of discontinuation periods, all showing statistically significant associations ($p < 0.05$).

Male participants were 0.24 times less likely to have successful TPT outcomes compared to female participants [AOR: 0.2391; 95% CI (0.0957, 0.5409)]. With increase in BMI, the participants had 1.0546 times chances of having successful outcomes [AOR: 1.1546; 95% CI (1.0172, 1.3354); $p < 0.0001$]. Participants who completed $\geq 80\%$ of the treatment were 1.4278 times more likely to have successful outcomes [AOR: 1.4278; 95% CI (1.3666, 1.5036); $p < 0.0001$]. With increase in number of treatment discontinuation periods, the participants had 0.51 times less

likely chances of having successful outcomes [AOR: 0.5108; 95% CI (0.4084, 0.6256); $p < 0.0001$].

Table 45: Univariate and multiple Generalized Linear Mixed Model (GLMM)
logistic regression analysis for factors associated with successful TPT outcomes

Risk factors		GLMM UOR (CI)	p-value	GLMM AOR (95% CI)	p-value
Age		0.9370 (0.9147, 0.9599)	<0.0001	0.9424 (0.9176, 0.9679)	<0.0001
Employment status	Employed	1	-	-	-
	Unemployed	0.0634 (0.0082, 0.4887)	0.00811	-	-
Relationship with Index case	Partner	1	-	-	-
	Offspring	1.1834 (0.2880, 4.8629)	0.8153	-	-
	Other	0.5320 (0.1311, 2.1594)	0.3772	-	-
	Parent	0.1317 (0.0328, 0.5297)	0.0043	-	-
	Sibling	0.3314 (0.0455, 2.4123)	0.2755	-	-
Symptoms	Absent	1	-	-	-
	Present	0.0550 (0.0197, 0.1535)	<0.0001	-	-
Past history	Absent	1	-	-	-
	Present	0.0613 (0.0220 0.1708)	<0.0001	-	-
BCG Scar	Present	1	-	-	-
	Uncertain	0.0474 (0.0062, 0.3628)	0.00332	-	-
Duration of cigarette Smoking		0.9148 (0.8759, 0.9555)	<0.0001		-

Duration of Alcohol consumption		0.9167 (0.8749, 0.9605)	0.0002	-	-
Duration of Chewing tobacco		0.8647 (0.8152, 0.9173)	<0.0001	0.3109 (0.1267, 0.7632)	0.0643
Comorbidities	Absent	1	-	-	-
	Present	0.0674 (0.0241, 0.1882)	<0.0001	-	-
Duration between Index case diagnosis and TPT initiation in the HHC		0.7712 (0.6308, 0.9427)	<0.0001	0.7921 (0.6520, 0.9623)	0.0190
BMI		1.1252 (1.0103, 1.2533)	0.0319	-	-
Discontinuation days		0.8717 (0.8337, 0.9115)	<0.0001	-	-
Discontinuation Periods		0.2179 (0.1177, 0.4034)	<0.0001	-	-
Occupation of TB patients	Employed	1	-	-	-
	Unemployed	4.1912 (1.5904, 11.0454)	0.00375	-	-
Total treatment duration of TB patients		1.0096 (1.0025, 1.0168)	0.00793	-	-
Outcome of TB patients	Successful	1	-	1	-
	Unsuccessful	0.2818 (0.1125, 0.7059)	0.00686	0.3109 (0.1267, 0.7632)	0.0108

Abbreviations: GLMM: Generalised Linear Mixed Model; UOR: Unadjusted Odds

Ratio; AOR: Adjusted Odds Ratio; CI: Confidence Interval

Generalized Linear Mixed Model (GLMM) for logistic regression was done by taking Index case (TB patients) number as random effect in the model and completion of treatment status among TPT subjects was taken as response to the model. Univariate GLMM logistic regression results are presented for significant factors affecting the outcome and multiple GLMM logistic regression model was selected using forward selection method.

After adjusting for the TB patients, multiple logistic regression analysis revealed that Tuberculosis preventive treatment outcomes influenced by age, time taken between index case diagnosis and TPT initiation in the household contact and outcomes of TB patients.

In this study it was found that, with increase in Age, the participants had 0.9424 times less likely to have successful outcomes with a AOR of 0.9424[(95% CI: 0.9176, 0.9679); $p < 0.0001$]. With increase in duration between index case diagnosis and TPT initiation in HHC, the participants had 0.7921 times less likely to have successful outcomes with a AOR of 0.7921[(95% CI: 0.6520, 0.9623); $p = 0.0190$].

Household contacts of the index case with unsuccessful outcomes were 0.3109 times less likely to have successful TPT outcomes compared to the household contacts of the index cases with successful outcomes, with an AOR of 0.3109 (95% CI: 0.1267, 0.7632), with $p = 0.0108$.

DISCUSSION

Tuberculosis is a severe infectious disease that significantly impacts global health. Historical records indicate that TB has been afflicting human populations for over 15 thousand years.¹ Despite being both preventable and treatable, tuberculosis emerged as the infectious disease causing the second highest mortality globally in 2022.² Current estimates suggest that *M. tuberculosis* has infected approximately one-fourth of the global population.⁴ India is recognized as having the largest projected number of tuberculosis infections (TBI) globally. Approximately 350 to 400 million individuals in India are believed to be infected with TBI, which results in roughly 2.6 million newly diagnosed TB cases each year.⁶ The likelihood of developing TB is more than 25-fold for individuals who have been in contact with patients with confirmed TB infections, in comparison to the general population.^{5, 6} So it is essential to amplify and broaden initiatives and funding to improve the provision of Tuberculosis Preventive Treatment (TPT) among the household contacts of Index TB cases.

Table 1- 12: Socio demographic profile of study participants

In the present study, mean age of the 645 participants was 35.14±18.76 years. Majority (64.07%) participants were aged less than or equal to 40 years. Males (50.85%) and females (49.15%) were almost equally distributed. Similar findings were seen in the study that was done in Maharashtra¹⁴ which showed that 72.7% were aged less than or equal to 45 years and 51.9% participants were males.

In the present study, among 317 female participants, 5.36% were pregnant which is in line with the study done in Johannesburg (South Africa).⁵¹

In the current study, majority (62.79%) participants were married. 69.32% participants living in nuclear families and 67.6% participants living in pucca houses which was in line with the study done in Kerala²⁰ which showed that 72.2% participants were married, 94.7% living in nuclear families and 87.2% participants living in pucca houses.

In the current study, 37.67% participants were living in well-ventilated houses and 40.78% participants were living in the houses with overcrowding which was similar to the study done in Addis Ababa (Ethiopia)³⁴ where 37% participants were living in well- ventilated houses and 46% participants were living in the houses with overcrowding.

In the present study, majority (62.17%) participants were Hindus followed by Muslims (25.74%) and Christians (12.09%). Similar results were seen in the study done in India.⁵²

In current study, 15.04% participants were illiterates, 30.39% had completed primary level education, 23.72% had finished their high school level education, 24.34% had done their pre university course and 6.51% participants were graduated. Similar results were found in the study done in 3 districts of Tamil Nadu.⁵³

In the present study, 34.11% participants were employed with majority (64.89%) being unemployed which was similar to the study done in southern Ethiopia³³ which showed that 34.86% participants were employed. Another study done in Puducherry (Tamil Nadu)⁵⁴ showed that 90% participants were employed. Variations in the Employment status might be due to inclusion of both urban and rural areas in our study.

In the current study, 8.84% participants belonged to socio economic class I, 8.22% belonged to class IV and majority participants (82.94%) belonged to socio economic class II and III. Similar findings were seen in the study done in Bangalore (Karnataka).⁵⁵

Table 13- 15: Treatment outcome profile of study participants

In the present study, among 143 TB patients who were on TB treatment, treatment success (cured+ completed) was seen in majority (72.73%) participants, treatment failure was seen in 2.8% participants, loss to follow-up was seen in 3.5% participants. 18.88% participants died during the treatment. Treatment regimen was changed in 2.1% participants. Similar findings were seen in the study done in Kerala²⁰, where treatment success (cured+ completed) was seen in majority (87.8%) participants, treatment failure was seen in 3.6% participants, loss to follow-up was seen in 2.8% participants and 3.6% participants died during the treatment.

In current study, among 502 household contacts who were put on TPT, 93.83% participants had completed the treatment, 2.59% participants discontinued the treatment due to toxicity, loss to follow- up was seen in 1.79% participants, 1% participants developed tuberculosis indicating treatment failure and 0.8% participants died during the TPT treatment. Similar results were seen in the study done in Srilanka⁵⁶ which showed that the treatment was completed by 90% participants, loss to follow- up was seen in 2.2% participants, 4.4% participants developed tuberculosis and 3.4% participants discontinued the treatment due to toxicity.

Table 16- 19: Association between Socio demographic factors and Tuberculosis treatment outcomes

In the current study, 93.75% participants in the age group of 21- 30 years and all the participants in the age group of 11- 20 years had successful outcomes. Participants who are less than or equal to 10 years and greater than or equal to 60 years had more unsuccessful outcomes. Significant association was found between age and tuberculosis treatment outcomes ($p < 0.05$). Similar associations were seen in the studies done in Bangalore⁵⁵ and Bangladesh⁵⁷ where more unsuccessful outcomes were seen among the participants aged less than or equal to 15 years and more than or equal to 50 years respectively.

In the present study, 86.44% females had successful outcomes when compared to 63.1% males. Significant association was found between gender and tuberculosis treatment outcomes ($p < 0.05$) which was similar to the studies done in Catalonia (Spain)²³ and Puducherry.⁵⁴

In the present study, 75.15% literates had successful outcomes when compared to 56.67% illiterates. Significant association was found between literacy status and tuberculosis treatment outcomes ($p < 0.05$). Similar association was seen in the studies done in Maharashtra²⁷ and Addis Ababa (Ethiopia).³⁴

In the present study, 94.74% unmarried participants had successful outcomes when compared to 71.03% married participants. Significant association was found between marital status and tuberculosis treatment outcomes ($p < 0.05$) which was similar to the study done in Tamil Nadu⁵³. Where as another study done in Bangalore⁵⁵ showed that more successful outcomes were seen in married participants compared to

unmarried or single. Behavioural patterns are likely to affect successful outcomes compared to marital status alone.⁵⁸

Table 20: Association between total treatment duration and tuberculosis treatment outcomes.

In the current study, Total duration of treatment was more among the participants with successful outcomes (172.15 ± 17.86 days) when compared to the participants with unsuccessful outcomes which was 70.62 ± 57.13 days. Significant association was found between total treatment duration and tuberculosis treatment outcomes ($p < 0.05$) which was similar to the study done in Maharashtra.²⁷

Table 21- 25: Association between Socio demographic factors and Tuberculosis preventive treatment outcomes

In the current study, 97.89% participants aged less than or equal to 50 years had successful outcomes when compared to 55.28% participants aged greater than or equal to 50 years. Significant association was found between age and tuberculosis treatment outcomes ($p < 0.05$) which was similar to the study done in Delhi.²⁵

In the present study, 99.34% employed participants had successful outcomes when compared to 91.43% unemployed participants. Significant association was found between employment status and tuberculosis treatment outcomes ($p < 0.05$) which showed that employment status of the participants influences the outcomes of the treatment. This was similar to the study done in Bangladesh.⁵⁷

In the current study, 97.07% literates had successful outcomes compared to 82.09% illiterates. Significant association was found between literacy status and tuberculosis treatment outcomes ($p < 0.05$) which showed that higher literacy status

was associated with successful outcomes. Similar association was found in the studies done in Bangladesh⁵⁷ and Kerala.²⁰

In the present study, 94.82% Hindus and 96.18% Muslims had successful outcomes when compared to 83.87% Christians. Significant association was found between literacy status and tuberculosis treatment outcomes ($p < 0.05$) which was similar to the study done in Bangalore⁵⁵ where more successful outcomes were seen among Muslims and Christians compared to Hindus. Religious and cultural factors influence the treatment adherence which makes them both barriers and enablers in achieving the successful outcomes.⁵⁹

In the current study, 96.84% offspring (Relation to index case) had successful outcomes when compared to 85.19% parents, 92.86% siblings and 95.45% partners. Significant association was found between relation to index case and treatment outcomes ($p < 0.05$) which was similar to the study done in Srilanka⁵⁶. Another study done in Tamil Nadu⁵³ showed that spouse relation was associated with unsuccessful outcomes compared to other relations to index case. Close contact to the index case increases the risk of infection which further increase the nonadherence to treatment which leads to more unsuccessful outcomes.³²

Table 26: Association between symptoms and tuberculosis preventive treatment outcomes

In the present study, all the participants with both cough as well as fever, 31.8% participants with cough and 35.4% participants with fever had unsuccessful outcomes when compared to 3.3% participants with no symptoms. Significant association was found between symptoms and tuberculosis preventive treatment outcomes ($p < 0.05$). Similar association was found in the study done in Srilanka⁵⁶ which showed that

participants with symptoms were associated with unsuccessful outcomes compared to the participants with no symptoms as they are at high risk of developing disease.

Table 27, 28: Association between comorbidities and tuberculosis preventive treatment outcomes

In the current study, 20.73% participants with both hypertension as well as diabetes and 41.48% participants with asthma had unsuccessful outcomes when compared to 1.86% participants with no comorbidities. 23.71% participants on anti-hypertensive and anti-diabetic medication had unsuccessful outcomes when compared to 2.11% participants with no history of any medication intake for other disease. Significant association was found between history of comorbidities and tuberculosis preventive treatment outcomes ($p < 0.05$) which was similar to the studies done in Bangalore⁵⁵ and Bangladesh⁵⁷ which showed that concomitant comorbidities and pill burden effects the outcomes of the treatment.

Table 29: Association between presence of BCG scar and tuberculosis preventive treatment outcomes

In the present study, 94.35% participants with BCG scar had successful outcomes compared to 50% participants with uncertain BCG scar status. Significant association was found between presence of BCG scar and tuberculosis preventive treatment outcomes ($p < 0.05$) which was in line with the studies done in Addis Ababa (Ethiopia)³⁴, Tamil Nadu⁵³ and Srilanka⁵⁶ which showed that presence of BCG scar was a protective factor and enables in achieving successful outcomes.

Table 30: Association between Cigarette smoking and tuberculosis preventive treatment outcomes

In the current study, duration of cigarette smoking was more among the participants with unsuccessful outcomes (7.74 ± 11.77 years) when compared to the participants with successful outcomes (1.39 ± 5.28 years). Significant association was found between duration of cigarette smoking and tuberculosis preventive treatment outcomes ($p < 0.05$) which was in line with the studies done in Catalonia (Spain)²³ and Bangalore⁵⁵ which showed that chronic cigarette smoking was associated with unsuccessful outcomes. It increases the resistance to drugs, drug related adverse effects, decreases the immunity which increases the risk of developing the disease.²⁵

Table 31: Association between Alcohol consumption and tuberculosis preventive treatment outcomes

In the present study, duration of alcohol consumption was more among the participants with unsuccessful outcomes (6.68 ± 10.89 years) when compared to the participants with successful outcomes (1.24 ± 4.85 years). Significant association was found between duration of alcohol consumption and tuberculosis preventive treatment outcomes ($p < 0.05$) which was in line with the study done in Bangalore.⁵⁵ Chronic and regular alcoholic uptake increases the noncompliance to drugs leading to unsuccessful outcomes.⁵⁷

Table 32: Association between chewing tobacco and tuberculosis preventive treatment outcomes

In the present study, duration of chewing tobacco was more among the participants with unsuccessful outcomes (6.26 ± 10.7 years) when compared to the participants with successful outcomes (0.7 ± 3.52 years). Significant association was

found between duration of chewing tobacco and tuberculosis preventive treatment outcomes ($p < 0.05$) which was in line with the study done in 8 high TB burden countries.³²

Table 33: Association between duration between Index case diagnosis and tuberculosis preventive treatment initiation in the Household contacts and Tuberculosis preventive treatment outcomes

In the present study, duration between index case diagnosis and TPT initiation was less among the participants with successful outcomes (16.97 ± 2.43 days) when compared to the participants with unsuccessful outcomes (18.23 ± 1.98 days). Significant association was found between duration between Index case diagnosis and tuberculosis preventive treatment initiation in the Household contacts and tuberculosis preventive treatment outcomes ($p < 0.05$) which was similar to the study done in Bishkek (Kyrgyz republic)¹⁶ which showed that 35% of the participants were put on TPT within 15 days of diagnosis of index case and associated with successful outcomes.

Table 34: Association between counselling regarding side effects of Tuberculosis preventive treatment and tuberculosis preventive treatment outcomes

In the current study, 94.2% participants who received counselling regarding side effects of tuberculosis preventive treatment had successful outcomes. Significant association was found between duration between counselling regarding side effects of Tuberculosis preventive treatment and tuberculosis preventive treatment outcomes ($p < 0.05$) which was in line with the study done in West Bengal.¹² Proper counselling and education regarding treatment screening, initiation of treatment, possible side effects, adherence and completion of treatment increases the successful outcomes.²⁸

Table 35: Association between Body Mass Index (BMI) and Tuberculosis preventive treatment outcomes

In the current study, BMI was high among the participants with successful outcomes ($23.87 \pm 3.4 \text{ kg/m}^2$) when compared to the participants with unsuccessful outcomes ($22.58 \pm 3.19 \text{ kg/m}^2$). Significant association was found between duration between BMI and tuberculosis preventive treatment outcomes ($p < 0.05$) which was in line with the study done in Delhi²⁵ and Kampala (Uganda)²⁹ which showed that improvement in nutrition improves the treatment outcomes.

Table 36: Association between Duration of follow-up and Tuberculosis preventive treatment outcomes

In the present study, duration of follow-up was more among the participants with successful outcomes (15.9 ± 1.6 months) when compared to the participants with unsuccessful outcomes (14.19 ± 3.54 months). Significant association was found between duration between BMI and tuberculosis preventive treatment outcomes ($p < 0.05$). Similar association was seen in the study done in Eswatini.⁶⁰ Regular monitoring of the participants on treatment increases the compliance to the treatment which further increases the successful outcomes.¹⁴

Table 37: Association between total tablets consumed and Tuberculosis preventive treatment outcomes

In the current study, total tablets consumed were more among the participants with successful outcomes (166.03 ± 7.72) when compared to the participants with unsuccessful outcomes (121.71 ± 22.57). Significant association was found between duration between total tablets consumed and tuberculosis preventive treatment outcomes ($p < 0.05$) which was in line with the study done in Srilanka.⁵⁶ Treatment

completion is one of the important factors that determines the successful outcomes and prevention of development of disease.¹⁹

Table 38: Association between number of discontinuation periods and Tuberculosis preventive treatment outcomes

In the present study, number of discontinuation periods were more among the participants with unsuccessful outcomes (7.48 ± 1.77) when compared to the participants with successful outcomes (4.14 ± 1.47). Significant association was found between duration between number of discontinuation periods and tuberculosis preventive treatment outcomes ($p < 0.05$) which was in line with the study done in Maharashtra.²⁷

Table 39: Association between duration of treatment discontinuation and Tuberculosis preventive treatment outcomes

In the current study, total duration of treatment discontinuation was more among the participants with unsuccessful outcomes (53.97 ± 20.06 days) when compared to the participants with successful outcomes (23.73 ± 10.9 days). Significant association was found between duration between duration of treatment discontinuation and tuberculosis preventive treatment outcomes ($p < 0.05$) which was similar to the study done in nine countries.⁶¹

Table 40: Association between reasons for discontinuation of Tuberculosis preventive treatment and treatment outcomes

In the present study, 62.5% participants with cough as well as fever, 50% participants with no family support and 22.2% participants with gastro intestinal symptoms who discontinued the treatment had unsuccessful outcomes. Significant

association was found between duration of treatment discontinuation and tuberculosis preventive treatment outcomes ($p < 0.05$) which was similar to the study done in Delhi.²⁵ Presence of symptoms, adverse effects and no family support were associated discontinuation of treatment which leads to more unsuccessful outcomes and behaves as barriers for TPT care cascade.¹⁴

Table 42: Multiple logistic regression analysis of the factors associated with successful tuberculosis treatment outcomes

In the present study, it was seen that high literacy status and inadequate treatment duration were the risk factors affecting the successful tuberculosis treatment outcomes. Similar findings with respect to literacy and treatment duration and different findings with respect to literacy status were seen in the studies done in Maharashtra²⁷, Addis Ababa (Ethiopia)³⁴ and Bangalore.⁵⁵ Work load, stress and forgetting to take the medication regularly among the employed might be the reasons for more unsuccessful outcomes.⁵

Table 44: Multiple logistic regression analysis of factors associated with successful Tuberculosis Preventive Treatment outcomes

In the present study, it was seen that male gender, low BMI, intake of inadequate number of tablets and higher number of treatment discontinuation periods were the risk factors affecting the successful treatment outcomes. Similar findings were seen in the studies done in Delhi²⁵, Maharashtra²⁷, Kampala (Uganda)²⁹ and Srilanka.⁵⁶

Table 45: Univariate and multiple GLMM logistic regression analysis of factors associated with successful TPT outcomes

In the current study, after adjusting the factors for TB patients, it was seen that successful tuberculosis preventive treatment outcomes were influenced by older age, increased duration between index case diagnosis and TPT initiation among HHC and unsuccessful outcomes among TB patients. Similar findings were seen in the studies done in Delhi²⁵, West Bengal¹² and Puducherry.⁵⁴

CONCLUSION

In the present study, a total of 143 Index TB cases (TB patients) and 502 household contacts participated with almost equal distribution of males (50.85%) & females (49.15%) and majority (64.07%) being under the age of 40 years. Majority (62.17%) participants belonged to Hindu religion. 15.04% participants were illiterates, 34.11% participants were employed and majority (82.94%) belonged to socio economic class II and III.

Among 143 TB patients who were initiated on TB treatment, treatment success (cured+ completed) was seen in majority (72.73%) participants, treatment failure was seen in 2.8% participants, loss to follow-up was seen in 3.5% participants. 18.88% participants died during the treatment. Treatment regimen was changed in 2.1% participants. In our study, it was found that, among TB patients who were illiterates and also those TB patients who completed 6 months of tuberculosis treatment were more likely to have successful outcomes.

Among 502 household contacts who were started on TPT, incidence of tuberculosis was seen among 5 (0.99%) participants. 93.83% participants had completed the treatment, 2.59% participants discontinued the treatment due to toxicity, loss to follow- up was seen in 1.79% participants and 0.8% participants died during the TPT treatment.

Out of the total 502 participants who were put on TPT, 5 (0.99%) developed TB disease after the follow- up of at least one year. So, the **Incidence of TB in our study was 0.99%**. Among these five participants, four participants developed TB at the end of 6th month and one participant at the end of 4th month of TPT treatment. Out of 502

participants who were put on TPT, 497 (99.01%) did not develop the disease in our study. Based on the results of this study, TPT can be considered effective in preventing the development of active tuberculosis as indicated by the low incidence of TB cases in household contacts of TB patients.

Factors like old age, unemployment, illiteracy, parents of index case, presence of fever and cough, comorbidities like hypertension and diabetes, cigarette smoking, alcohol consumption, tobacco chewing, increased duration between index case diagnosis and TPT initiation among HHC, lack of counselling regarding side effects of TPT, low BMI, decreased duration of follow up, incomplete treatment and no family support were associated with unsuccessful tuberculosis preventive treatment outcomes. ($p < 0.05$)

With increase in BMI, the participants had 1.0546 times chances of having successful outcomes (AOR: 1.1546). Participants who completed $\geq 80\%$ of the treatment were 1.4278 times more likely to have successful outcomes (AOR: 1.4278). With increase in number of treatment discontinuation periods, the participants had 0.51 times less likely chances of having successful outcomes (AOR: 0.5108).

After adjusting the factors for TB patients (Generalized linear mixed model), it was found that, increasing age, increase in duration between index case diagnosis and TPT initiation in HHC and index cases with unsuccessful TB outcomes lead to unsuccessful TPT outcomes among household contacts.

RECOMMENDATIONS

1. Based on the results of this study, TPT can be considered effective in preventing the development of active tuberculosis as indicated by the low incidence of TB cases in household contacts of TB patients
2. In addition to persistent and thorough monitoring of Tuberculosis patients and their close contacts, training the treatment supervisors or healthcare providers with the skills to carry out qualitative research in conjunction with observational and analytical research can enhance the reliability of understanding the determinants that affect treatment outcomes and can aid in identifying improved strategies for attaining more successful treatment outcomes.
3. Vigilant supervision, motivation and counselling/ education on preventive measures, significance of adhering to the treatment regimen, awareness of potential side effects, especially among the individuals facing financial difficulties, lack of familial support, adverse reactions to drugs, and heavy work responsibilities can reduce the instances of loss to follow-up and can reduce the transmission and progression of the disease

STRENGTHS

1. The study can provide valuable insights into the effectiveness of TPT among household contacts and improve the understanding of risk factors of unsuccessful outcomes of tuberculosis preventive treatment
2. Study participants were followed for at least one year which helped in assessment of TPT impact on incidence of TB.
3. In this study, participants who were enrolled for TPT under one DTC were included

LIMITATIONS

1. All the participants should have been followed up for at least two years to assess TPT's durability and long-term benefits in preventing tuberculosis
2. Qualitative studies could have been done to address more factors affecting the treatment outcomes.

SUMMARY

The present study was a longitudinal study undertaken to find the incidence of tuberculosis among household contacts on Tuberculosis Preventive Treatment (TPT). The study included a total of 625 participants, that is, 143 TB patients (Index cases) and 502 household contacts (HHC) registered under District TB Center (DTC), Belagavi who were chosen using universal sampling method. Duration of the study was from 1st October 2022 to 31st March 2024. Newly diagnosed TB patients were enrolled for the first 6 months, household contacts of the TB patients were interviewed using a pre designed and pre tested questionnaire after taking the informed consent. HHC were screened for TB symptoms and were put on TPT (6 months of Isoniazid) among the participants with no TB disease were followed up till 31st March 2024.

A total of 143 Index TB cases (TB patients) and 502 household contacts participated with almost equal distribution of males (50.85%) & females (49.15%) and majority (64.07%) being under the age of 40 years. Majority (62.17%) participants belonged to Hindu religion. 15.04% participants were illiterates, 34.11% participants were employed and majority (82.94%) belonged to socio economic class II and III.

Among 143 TB patients who were initiated on TB treatment, treatment success (cured+ completed) was seen in majority (72.73%) participants, treatment failure was seen in 2.8% participants, loss to follow-up was seen in 3.5% participants. 18.88% participants died during the treatment. Treatment regimen was changed in 2.1% participants. In our study, it was found that, among TB patients who were illiterates

and also those TB patients who completed 6 months of tuberculosis treatment were more likely to have successful outcomes.

Among 502 household contacts who were started on TPT, incidence of tuberculosis was seen among 5 (0.99%) participants. 93.83% participants had completed the treatment, 2.59% participants discontinued the treatment due to toxicity, loss to follow-up was seen in 1.79% participants and 0.8% participants died during the TPT treatment.

Out of the total 502 participants who were put on TPT, 5 (0.99%) developed TB disease after the follow-up of at least one year. So, the **Incidence of TB in our study was 0.99%**. Among these five participants, four participants developed TB at the end of 6th month and one participant at the end of 4th month of TPT treatment. Out of 502 participants who were put on TPT, 497 (99.01%) did not develop the disease in our study. Based on the results of this study, TPT can be considered effective in preventing the development of active tuberculosis as indicated by the low incidence of TB cases in household contacts of TB patients.

Factors like old age, unemployment, illiteracy, parents of index case, presence of fever and cough, comorbidities like hypertension and diabetes, cigarette smoking, alcohol consumption, tobacco chewing, increased duration between index case diagnosis and TPT initiation among HHC, lack of counselling regarding side effects of TPT, low BMI, decreased duration of follow up, incomplete treatment and no family support were associated with unsuccessful tuberculosis preventive treatment outcomes. ($p < 0.05$)

With increase in BMI, the participants had 1.0546 times chances of having successful outcomes (AOR: 1.1546). Participants who completed $\geq 80\%$ of the

treatment were 1.4278 times more likely to have successful outcomes (AOR: 1.4278).

With increase in number of treatment discontinuation periods, the participants had 0.51 times less likely chances of having successful outcomes (AOR: 0.5108).

After adjusting the factors for TB patients (Generalized linear mixed model), it was found that, increasing age, increase in duration between index case diagnosis and TPT initiation in HHC and index cases with unsuccessful TB outcomes lead to unsuccessful TPT outcomes among household contacts.

Based on the results of this study, TPT can be considered effective in preventing the development of active tuberculosis as indicated by the low incidence of TB cases in household contacts of TB patients

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ANNEXURE – I

INFORMED CONSENT FORM

“INCIDENCE OF TUBERCULOSIS AMONG HOUSEHOLD CONTACTS ON TUBERCULOSIS PREVENTIVE TREATMENT- A LONGITUDINAL STUDY”

Introduction: You are being invited to participate in this study to find out “Incidence of Tuberculosis among household contacts on Tuberculosis Preventive Treatment”.

Tuberculosis elimination is a big concern in India. To eliminate tuberculosis, besides treatment of the cases, prevention of spread of the disease to contacts and high-risk population is equally important. Few studies reported that, treatment of latent tuberculosis infection cases and contacts with Tuberculosis Preventive Treatment reduced the incidence of tuberculosis in them. Proper follow up of the population who are on TPT regimen is needed to know the incidence of tuberculosis and the reasons for non-adherence and loss to follow up. Hence the present study is undertaken. Participation in this study is completely voluntary.

Explanation of procedure: In this study, you will have to answer a few prepared questions about socio demographic details, treatment related factors, clinical history and treatment follow up details. If you agree to participate, then only questions will be asked to you. At any moment, you can withdraw from the study. Information will be collected using pre-tested, pre-designed questionnaire.

Withdrawal from participation in the study: Participation in this study is voluntary. You will be free to decide whether to participate in this study or continue

participation once enrolled. In case you decide to withdraw your participation, you are free to do so. However, please convey the decision to the principal investigator.

Possible benefits from participating in the study: You will/will not have nor get any benefits by participating in this study. The data gathered will help the population at large. Possible risks from participating in the study: There are no risks involved in participating in this study.

Privacy and confidentiality: The information collected from you will be coded, to prevent any person from identifying you. Your identity will never be revealed. The data collected from you will be kept confidential and only processed or aggregated data will be used for publication.

Financial incentives: You will not receive any payment for participating in this study.

Authorization for publication of aggregated data: Results obtained after processing of the aggregated data will be published for scientific purposes and or presented to scientific groups. However, your identity will never be revealed.

Legal rights: By signing this consent form, we are not waving any of your legal rights.

CONSENT STATEMENT

I am making a voluntary decision to participate in the study “Incidence of tuberculosis Among household contacts on tuberculosis preventive treatment- a longitudinal study.” My signature below indicates that I have decided to participate and I have read the information provided above or the information provided above has been read to me in the language that I understand best. I was given the opportunity to ask questions and that they have been answered to my satisfaction.

Name of the Participant:

Signature or left thumb impression of the participant:

Name of the witness:

Signature or left thumb impression of the witness:

Name of the investigator:

Signature of the investigator:

Date: _____

Place: _____

Assent (<18 years)

‘Incidence of Tuberculosis among household contacts on Tuberculosis Preventive Treatment – A Longitudinal study’

I have read the information in this form. After understanding all details about the study, I agree to give assent to be included as a volunteer in the study titled “Incidence of tuberculosis among household contacts on Tuberculosis Preventive Treatment”.

Name of the Participant

Signature of the participant

Or Left-Hand Thumb impression

Name of the Parent

Signature of the parent

Name of Investigator

Signature of investigator

Name of Witness

Signature of Witness

Date: _____

Place: _____

ANNEXURE – II

QUESTIONNAIRE

“INCIDENCE OF TUBERCULOSIS AMONG HOUSEHOLD CONTACTS ON
TUBERCULOSIS PREVENTIVE TREATMENT– A LONGITUDINAL STUDY.”

Sl. No:

Date of registration:

PART – A: INDEX CASE DETAILS

1. Index case number:
2. Name:
3. Age:
4. Gender: Male/ Female
5. Address:
6. Occupation: Employed / Unemployed
7. Education status: Illiterate/Primary/ High school PUC or Diploma/ Graduation
8. Marital status: Married/ Unmarried/ Widow/ Widower/ Divorcee
9. Pregnant: Yes/ No/ NA
10. Religion: Hindu/ Muslim/ Christian/ others specify_____
11. Family type: Nuclear/ Joint/ Broken/ Problem
12. Total number of family members:

13. Total income of family members per month: 14. Socio economic status: 1/ 2/ 3/ 4/ 5
15. Type of house: Kucha/ Semi – pucca/ Pucca
16. House well ventilated: Yes/No
17. Number of rooms:
18. Overcrowding: Yes/No
19. Type of TB: Sputum positive pulmonary TB/ Sputum negative pulmonary TB
20. Number of household contacts:
21. H/O cough: Yes/No. If yes, duration _____ days
22. Treatment duration on the day of interview: _____ days
23. Total duration of Anti tubercular treatment: _____ days
24. Treatment outcome: cured/ treatment failure/ loss to follow up/ Died/ not evaluated

PART – B: HOUSEHOLD CONTACT DETAILS

Socio demographic details

Index case number:

Household contact number:

1. Name:

2. Age: ____yrs.
3. Sex: Male / Female
4. Occupation: Employed / Unemployed
5. Education status: Illiterate/Primary/ High school PUC or Diploma/ Graduation
6. Marital status: Married/ Unmarried/ Widow/ Widower/ Divorcee
7. Pregnant: Yes/ No/ NA
8. Relation to Index case: Partner/ offspring/ sibling/ parent/ others specify
9. Duration of contact with index case: ____days
10. Sleep location: Share same bed/ share room but not bed/ different room

Clinical profile

1. Chief complaints:

- Cough: Present/ Absent

Dry/ Productive

Duration ____days

- Fever: Present/ Absent

Duration ____days

- Night sweats: Yes/ No

- Loss of weight: Yes/ No

- Breathing difficulty: Yes/ No
- Loss of appetite: Yes/No
- Generalized weakness: Present /Absent
- Others, specify _____

2. Past history: Hypertension/Diabetes / Tuberculosis /Asthma/ COPD / HIV /
IHD / Liver disease / Drug allergies/ renal disease

BCG scar: present/ absent/ uncertain

3. Personal history:

a) Habits:

Habits	Duration and frequency per week	If left, since how long
--------	---------------------------------	-------------------------

Beedi/cigarette smoking

Alcohol

Chewing tobacco

Others(specify):

b) Diet history: Vegetarian / Non-Vegetarian

4. Treatment History:

1. Past h/o TPT: Yes/No

If yes, duration of TPT _____days

2. Details of the treatment if taking for any other disease:

Anti-diabetic/ Anti-retro viral/ Corticosteroids/ Anti- hypertensive / Anti-malarial

5. Details of TPT treatment:

a) Eligible for TPT: Yes/No

b) Date of registration: _____

c) TPT started: Yes/ No

d) Date of starting treatment: _____

e) If TPT not started, reason: Children less than 5 years/ Second degree relative/

Smear negative index case/ stigma and discrimination

6. Treatment related factors

a) Support of treatment supervisor – Yes / No

b) Counselling regarding treatment duration – Done / Not Done

c) Counselling regarding side effects of drugs –Done / Not Done

Physical Examination:

I) General Physical Examination

1. Height: _____ cm

2. Weight: _____ Kg

3. BMI: _____ kg / m²

4. Pallor – Icterus – Cyanosis – Clubbing – Lymphadenopathy – Oedema

Investigation profile:

Name of test

Result

Sputum microscopy

CBNAAT

Chest X-ray

Tuberculin Skin Testing (children less than 6 years)

Investigations for the complications if any: Hb%/CBC/LFT/RFT/Ultrasound

Others if any, specify_____

PART – C: FOLLOW UP DETAILS.

Month of follow up	1	2	3	4	5	6	7	8	9
	10	11	12						

Discontinued the treatment? 1. Yes 2. No

If yes, duration in days: _____

Reasons for discontinuation? * _____

If discontinued, restarted the treatment? 1. Yes 2. No

If yes, after how many days?

Side effects of the drugs, if any*

Primary symptoms, if any: 1. Fever 2. Cough 3. Night sweats 4. Weight loss

Duration of symptoms in days:

If symptomatic, investigation report

1. Sputum examination

2. CBNAAT 3. X – RAY

4. Any others specify_

Investigations if any complications: 1. Hb%, 2. LFT, 3. RFT, 4. USG, 5. Others

Supervision by health supervisor? 1. Yes 2. No

Still in contact with the TB case? 1. Yes 2. No

If yes, duration of contact in days

Does your family support you in the treatment? 1. Yes 2. No

*Reasons for discontinuation: 1 – side effects of the drugs, 2 – No family support

3 – No proper monitoring and supervision by Health worker, 4 – Duration of treatment 5 – Stigma and discrimination, 6 – Work load, 7 – Difficulty in remembering to take the drug 8 – Non availability of drugs, 9 – others if any specify_

*Side effects of the drugs: 1 – Skin rash /malar rash, 2 – Numbness or tingling sensation of fingers/toes, 3 – Yellowing of eyes or skin, 4 – Lethargy and sleepiness

5 – Pellagra (dementia/diarrhea/dermatitis), 6 – Joint pains, 7 – general side effects like nausea/gastritis/abdominal discomfort/ Fever/loss of appetite, 8 – If any others specify_

PART – D: END OF FOLLOW UP

1. Total number of doses consumed ____
2. Total duration of treatment _____ days

Treatment outcome: TPT completed/ TPT failed/ loss to follow up/ TPT discontinuation due to toxicity/ died/ not evaluated

ANNEXURE- III

Key to Master Chart

“INCIDENCE OF TUBERULOSIS AMONG HOUSEHOLD CONTACTS ON
TUBERCULOSIS PREVENTIVE TREATMENT– A LONGITUDINAL STUDY.”

TB patients

- A. Month of registration: October- 1/ November- 2/ December- 3/ January- 4/
February- 5/ March- 6
- B. Age: in years
- C. Gender: Male- 1/ Female- 2
- D. Address: Rural- 1/ Urban- 2
- E. Occupation: Employed- 1 / Unemployed- 2
- F. Education status: Illiterate- 1/Primary- 2/ High school- 3/ PUC- 4/ Diploma or
Graduation- 5
- G. Marital status: Married- 1/ Unmarried- 2/ Widow- 3/ Widower- 4/ Divorcee- 5
- H. Pregnant: Yes- 1/ No- 0
- I. Religion: Hindu- 1/ Muslim- 2/ Christian- 3
- J. Family type: Nuclear- 1/ Joint- 2
- K. Total number of family members:
- L. Socio-economic status: 1/ 2/ 3/ 4/ 5

- M. Type of the house: Kucha- 1/ Semi – pucca- 2/ Pucca- 3
- N. House well-ventilated: Yes- 1/No- 0
- O. Overcrowding: Yes- 1/No- 0
- P. Type of TB: Sputum positive pulmonary TB- 1/ Culture positive pulmonary TB- 2
- Q. Number of household contacts:
- R. Treatment duration on the day of interview: _____ days
- S. Total treatment duration: _____ days
- T. Treatment outcome: cured- 1/ treatment failure- 2/ treatment completed- 3/ loss to follow up- 4/ Died- 5/ Treatment regimen changed- 6

HHC details

Socio-demographic details

- A. Index case number:
- B. Age: in years
- C. Sex: Male- 1 / Female- 2
- D. Occupation: Employed- 1 / Unemployed- 2
- E. Education status: Illiterate- 1/Primary- 2/ High school- 3/ PUC- 4/ Diploma or Graduation- 5
- F. Marital status: Married- 1/ Unmarried- 2/ Widow- 3/ Widower- 4/ Divorcee- 5

G. Pregnant: Yes- 1/ No- 2

H. Relation to Index case: Partner- 1/ offspring- 2/ sibling- 3/ parent- 4/ others- 5

I. Sleep location: Share same bed- 1/ share a room but not bed- 2/ different room- 3

Symptoms

J. No symptoms- 0/ Cough < 2 weeks- 1/ Cough > 2 weeks- 2/ Fever < 2 weeks- 3/ Fever- > 2 weeks- 4/ Night sweats- 5/ Loss of weight- 6/ Breathing difficulty- 7/ Loss of appetite- 8/ Generalized weakness- 9/ Cough+ fever < 2 weeks- 10/ Multiple- 11

Past history:

K. None- 0/ Hypertension- 1/ Diabetes- 2/ Tuberculosis- 3/ skin lesions- 4/ COPD- 5/ HIV- 6/ IHD- 7/ Liver disease- 8/ DM+ HTN- 9/ renal disease - 10/ Asthma- 11

L. BCG scar: present- 1/ uncertain- 2/ absent- 0

M. Duration of cigarette smoking: in years

N. Duration of Alcohol: in years

O. Duration of chewing tobacco/ beetle nut: in years

P. Diet: vegetarian- 1/ non-vegetarian- 2

Q. Duration of TPT in the past: in days

R. Outcome of TPT in the past: Not applicable- 0/ Completed- 1/ Failed- 2/ Loss to follow-up- 3/ Discontinuation due to toxicity- 4/ Died- 5/ Not evaluated- 6

Details of the treatment any other disease:

S. None- 0/ Anti- hypertensive- 1/ Anti-diabetic- 2/ Anti-retro viral- 3/ Anti-hypertensive and anti-diabetic- 4

Details of TPT treatment:

T. Duration between Index case diagnosis and TPT initiation in the HHC: in days

Treatment related factors

U. Support of treatment supervisor: Yes- 1/ No- 0

V. Counselling regarding treatment duration: Done- 1 / Not Done- 0

W. Counselling regarding side effects of drugs: Done- 1 / Not Done- 0

Physical Examination:

General Physical Examination

X. BMI: in kg/ m²

Investigation profile:

Y. Sputum microscopy- 1/ sputum+ CBNAAT- 2/ Chest X-Ray- 3/ TST- 4

Z. Result: positive- 1/ negative- 2

Follow up details

AA. Months of follow up: in months

AB. Total treatment duration: in days

AC. Total tablets consumed:

AD. Number of discontinuation periods:

AE. duration of discontinuation: in days

AF. Reasons for discontinuation:

None- 0/ GI related (Nausea, vomiting, abdominal discomfort)- 1/ cough- 2/ fever- 3/
Loss of appetite- 4/ Drowsy and tired- 5/ No symptoms during the prophylaxis period-
6/ Duration of treatment+ non-symptomatic- 7/ No family support- 8/ No proper
monitoring and supervision by Health worker- 9/ Stigma and discrimination- 10/
Workload- 11/ Non availability of drugs- 12/ Forgot to take- 13/ Fever and cough- 14

AG. Investigations: Sputum microscopy- 1/ sputum+ CBNAAT- 2/ Chest X-Ray- 3/
TST- 4/ CBC- 5/ LFT- 6/ CBC+LFT- 7/ CBC+ LFT+ USG- 8

AH. Result: Not applicable- 0/ Positive or Abnormal- 1/ Negative or Normal- 2

AI. Treatment outcome: Completed- 1/ Failed- 2/ Loss to follow-up- 3/

Discontinuation due to toxicity- 4/ Died- 5/ Not evaluated- 6

Annexure IV (Master chart) part 1: TB patients' data (n= 143)

Month of Registration	Age	Gender	Address	Occupation	Education status	Marital status	Pregnant	Religion	Family type	Total number of family members	Socioeconomic status	Type of house	House well-ventilated or not	Overcrowding	Type of TB	Number of household contacts	Treatment duration on the day of interview	Total treatment duration	Treatment outcome
1	21	1	2	2	3	2	0	1	1	4	2	3	0	0	1	3	26	167	1
1	14	2	2	2	2	2	0	2	1	4	2	3	0	0	1	3	32	167	1
1	14	2	2	2	3	2	0	1	1	6	1	3	0	1	1	5	22	167	3
1	22	2	2	2	4	2	0	1	1	4	2	3	0	0	1	3	15	167	1
1	22	2	2	2	4	1	1	2	1	2	2	3	1	0	1	1	16	167	3
1	34	1	2	1	3	1	0	1	1	5	3	2	0	1	1	4	19	181	5
1	36	2	2	2	4	1	0	1	1	6	2	3	0	1	1	5	17	222	1
1	40	2	2	2	3	1	0	1	1	4	3	3	1	0	1	3	11	167	3
1	43	1	2	1	4	1	0	2	1	5	2	3	1	0	1	4	21	167	1
1	46	1	2	2	3	1	0	1	2	4	4	3	0	0	1	3	21	33	5
1	60	1	2	2	3	1	0	1	1	6	2	3	0	1	1	5	11	167	1
1	61	1	2	2	2	1	0	3	1	6	3	3	0	1	1	5	14	50	5
1	63	1	2	2	1	4	0	1	1	3	3	3	1	0	1	2	13	167	3
1	67	1	2	2	1	1	0	1	1	4	2	3	1	0	1	3	19	29	5
1	71	1	2	2	1	1	0	2	1	3	3	3	1	0	1	2	21	167	1
2	18	2	2	2	3	2	0	1	1	5	1	3	1	0	1	4	27	167	3
2	24	1	2	1	4	2	0	1	1	4	2	3	0	0	1	3	15	167	1
2	25	1	2	2	4	2	0	2	1	4	3	3	0	0	1	3	16	167	3
2	29	2	2	1	5	1	0	1	1	5	1	3	0	1	1	4	12	167	1
2	29	2	2	2	5	1	0	3	1	3	1	3	1	0	1	2	12	167	1
2	32	2	2	1	5	1	0	3	1	4	2	3	0	0	1	3	21	167	3
2	32	2	2	1	3	1	0	1	1	4	2	3	0	0	1	3	11	167	3
2	33	1	2	1	3	1	0	1	1	5	2	3	0	1	1	4	15	93	5
2	33	2	2	2	2	1	0	3	1	2	2	3	1	0	1	1	21	167	1
2	33	1	2	2	2	1	0	2	1	4	2	3	0	0	1	3	25	167	1
2	36	1	2	1	4	1	0	1	1	4	3	3	0	0	1	3	14	167	3
2	37	1	2	1	5	1	0	1	2	4	4	3	1	0	1	3	19	167	5
2	39	1	2	1	4	1	0	1	1	5	3	3	0	0	1	4	10	167	1
2	40	1	2	2	3	1	0	2	1	6	2	3	0	1	1	5	13	174	1
2	42	2	2	1	4	1	0	1	1	5	2	3	1	1	1	4	9	167	1
2	44	1	2	1	4	1	0	1	1	4	2	2	1	0	1	3	23	62	5
2	53	2	2	1	2	1	0	1	1	3	2	3	0	0	1	2	24	167	1
2	58	1	2	1	1	1	0	1	1	6	2	3	0	1	1	5	21	47	5
2	61	1	2	1	2	4	0	2	1	5	3	3	1	0	1	4	17	44	5
2	66	1	2	1	2	1	0	1	1	5	2	3	0	1	1	4	15	49	5
3	6	2	2	1	1	2	0	1	1	3	2	3	1	0	1	2	22	167	1
3	8	2	2	2	2	2	0	1	1	4	2	3	0	0	1	3	15	44	5
3	16	2	2	1	3	2	0	1	2	2	3	3	1	0	1	1	26	167	3
3	21	2	2	2	4	2	0	1	1	2	1	3	1	0	1	1	21	167	1
3	23	2	2	1	4	1	0	3	2	2	3	3	0	0	1	1	27	167	1
3	24	1	2	1	4	2	0	1	1	3	2	3	0	0	1	2	13	167	1
3	25	2	2	2	3	1	0	1	1	4	3	2	0	0	1	3	19	167	3
3	26	2	2	1	3	1	1	2	1	4	1	3	0	0	1	3	11	44	5
3	26	2	2	1	4	1	0	1	1	6	2	3	0	1	1	5	13	167	1
3	27	2	2	1	5	1	0	2	1	5	3	3	1	0	1	4	13	282	1
3	28	2	2	2	4	1	1	1	2	4	3	3	0	0	1	3	12	167	3
3	31	2	2	1	4	1	0	1	1	4	3	3	0	0	1	3	11	223	2
3	31	2	2	1	4	1	0	2	1	4	3	3	1	0	1	3	9	169	1
3	33	1	2	1	3	1	0	1	1	7	2	3	0	1	1	6	17	77	4
3	35	1	2	1	3	1	0	2	1	3	2	3	1	0	1	2	22	40	5
3	37	2	2	1	5	1	0	1	1	4	2	3	1	0	1	3	10	167	1
3	50	1	2	2	3	1	0	2	1	9	3	3	0	1	1	8	21	169	1
3	52	2	2	2	2	1	0	1	1	4	2	3	0	0	1	3	22	219	1
3	54	1	2	2	1	1	0	1	1	4	2	3	1	0	1	3	19	15	5
3	54	1	2	2	1	4	0	1	1	3	2	3	0	0	1	2	13	15	5
3	55	1	2	2	1	4	0	2	1	4	2	3	1	0	1	3	16	55	4
3	61	2	2	1	1	3	0	1	1	5	2	3	0	0	1	4	22	167	3
3	61	2	2	2	1	1	0	1	1	5	3	3	0	0	1	4	21	48	5
3	68	1	2	2	1	1	0	3	2	4	4	3	1	0	1	3	12	24	5
3	69	2	2	1	1	3	0	2	1	2	2	3	0	0	1	1	22	167	1
3	76	1	2	1	1	4	0	2	1	2	2	3	0	0	1	1	18	167	3
4	19	2	2	1	3	1	0	2	1	2	1	2	1	0	1	1	22	167	1
4	23	2	2	1	4	2	0	1	1	3	2	3	1	0	1	2	11	168	1
4	34	1	2	1	3	1	0	1	1	6	2	3	0	1	1	5	8	167	3
4	40	2	2	2	3	1	0	1	1	4	2	3	0	0	1	3	15	48	5
4	41	1	2	1	4	1	0	1	1	4	3	3	1	0	1	3	11	167	1
4	42	1	2	1	4	1	0	1	1	3	2	3	0	0	1	2	11	167	3
4	42	1	2	1	4	1	0	3	1	3	2	3	1	0	1	2	12	167	1
4	42	2	2	1	4	1	0	1	1	2	3	3	1	0	1	1	11	167	3

Annexure IV (Master chart) part 1: TB patients' data (n= 143)

4	53	2	2	2	2	3	0	1	2	5	3	3	1	0	1	4	21	54	5
4	63	1	2	2	3	4	0	3	1	4	2	3	0	0	2	3	17	167	1
4	64	1	2	1	3	1	0	1	1	3	3	2	1	0	1	2	18	3	5
4	73	1	2	1	1	4	0	1	1	2	2	3	1	0	1	1	15	167	3
5	29	1	2	1	5	1	0	1	1	3	1	2	1	0	1	2	15	168	3
5	36	1	2	2	5	1	0	2	1	4	2	3	0	0	1	3	12	182	2
5	37	1	2	1	4	1	0	3	1	3	3	3	0	0	1	2	16	41	4
5	40	1	2	2	3	1	0	1	1	3	3	2	0	0	1	2	18	77	5
5	45	1	2	1	5	1	0	1	1	5	2	3	0	0	1	4	25	179	2
5	45	1	2	2	3	1	0	3	1	7	2	3	0	1	1	6	23	167	1
5	46	1	2	1	4	1	0	1	1	3	2	3	0	0	1	2	12	167	1
5	51	1	2	2	3	1	0	1	1	6	2	3	0	1	1	5	23	223	1
5	53	1	2	2	2	1	0	2	1	4	2	3	0	0	1	3	13	269	1
5	53	1	2	2	2	1	0	1	1	2	3	2	1	0	1	1	17	176	1
5	65	2	2	2	2	3	0	2	1	3	2	3	1	0	1	2	21	167	1
5	68	2	2	1	1	1	0	1	1	5	2	3	0	0	1	4	10	174	1
6	22	1	2	2	4	2	0	1	1	2	2	3	1	0	1	1	18	167	3
6	22	2	2	2	4	1	0	1	1	5	2	3	0	0	1	4	21	168	1
6	23	2	2	2	4	1	1	2	1	4	2	3	0	0	1	3	11	167	1
6	29	2	2	2	4	1	0	2	1	4	2	3	1	0	1	3	16	167	1
6	42	1	2	2	4	1	0	1	1	3	2	3	1	0	1	2	21	167	3
6	44	1	2	1	4	1	0	1	1	6	3	3	0	1	2	5	25	167	1
6	48	2	2	2	4	1	0	2	1	4	2	2	0	0	1	3	12	61	6
6	48	1	2	1	3	1	0	1	1	7	2	3	0	1	1	6	17	167	3
6	48	2	2	1	3	3	0	1	1	3	3	3	1	0	1	2	24	171	1
6	56	1	2	2	1	1	0	1	1	3	3	3	0	0	1	2	22	2	5
6	59	1	2	2	3	1	0	1	2	4	3	2	1	0	1	3	21	128	5
1	21	2	1	2	3	1	0	1	2	6	3	2	0	1	1	5	21	181	3
1	28	1	1	1	4	1	0	1	2	6	4	3	0	1	1	5	21	167	1
1	37	1	1	1	4	1	0	1	1	3	3	3	0	0	1	2	14	179	1
1	37	1	1	1	3	1	0	1	1	3	3	2	1	0	1	2	22	167	1
1	39	2	1	2	2	1	0	1	1	4	4	3	1	0	1	3	11	174	1
1	41	1	1	1	2	1	0	1	1	5	3	3	0	0	1	4	15	167	3
1	53	1	1	1	2	1	0	1	1	5	3	2	0	0	1	4	11	167	1
1	55	1	1	2	2	4	0	2	2	9	3	3	1	1	1	8	21	167	1
1	57	2	1	2	1	1	0	2	2	9	4	2	0	1	1	8	15	167	1
1	60	1	1	2	1	1	0	2	1	3	4	2	0	0	2	2	21	167	1
1	90	1	1	2	1	4	0	3	1	5	4	2	0	0	1	4	25	31	5
2	14	2	1	2	2	2	0	1	1	3	2	1	0	0	1	2	15	167	3
2	27	2	1	2	3	1	1	1	1	4	4	3	1	0	1	3	11	167	1
2	30	2	1	2	3	1	0	1	1	2	2	2	1	0	1	1	16	167	1
2	37	2	1	2	3	1	0	1	2	7	2	2	0	1	1	6	21	189	2
2	39	1	1	2	2	1	0	1	1	3	3	1	0	0	1	2	12	167	1
2	40	1	1	1	2	1	0	1	1	3	3	3	1	0	1	2	13	167	1
2	43	1	1	1	2	1	0	2	2	6	2	2	1	1	1	5	17	167	1
2	49	1	1	2	2	1	0	1	2	7	3	2	0	1	1	6	21	167	1
2	53	1	1	1	1	1	0	1	1	5	3	2	0	0	1	4	18	167	3
3	19	2	1	2	3	2	0	1	1	3	3	2	1	0	1	2	11	167	1
3	22	2	1	2	2	1	1	3	2	6	4	3	1	1	1	5	14	167	1
3	29	2	1	1	5	1	0	1	2	9	2	1	0	1	1	8	13	167	1
3	34	1	1	1	4	1	0	1	1	4	3	1	0	0	1	3	12	167	1
3	43	1	1	1	3	1	0	1	1	4	3	2	1	0	1	3	21	94	5
3	53	1	1	1	1	1	0	1	2	7	1	3	0	1	1	6	15	167	1
3	56	1	1	2	1	4	0	1	1	5	1	2	1	0	1	4	17	167	1
3	56	1	1	2	1	1	0	1	1	3	2	1	0	0	1	2	11	167	1
3	66	1	1	2	1	1	0	1	2	6	2	2	1	0	1	5	18	114	5
3	76	1	1	2	1	4	0	2	2	6	3	3	1	1	1	5	11	49	5
4	19	2	1	2	3	2	0	3	1	4	2	3	0	0	1	3	12	167	1
4	27	1	1	1	5	1	0	2	1	5	2	3	1	0	1	4	13	198	3
4	30	1	1	1	5	1	0	3	2	10	2	2	0	1	1	9	16	66	4
4	31	2	1	2	4	1	0	2	2	7	1	2	1	1	1	6	21	195	3
4	33	2	1	1	4	1	0	2	2	10	3	2	0	1	1	9	14	168	1
4	50	2	1	2	1	1	0	2	2	6	2	2	1	1	1	5	12	167	1
4	52	1	1	1	1	1	0	2	1	4	4	2	1	0	1	3	15	168	1
4	83	1	1	2	1	4	0	2	1	5	3	3	1	0	1	4	12	15	4
5	23	1	1	2	2	2	0	1	2	8	2	3	0	1	1	7	12	167	1
5	24	1	1	1	4	2	0	1	2	7	2	2	0	1	1	6	15	167	3
5	53	1	1	1	1	1	0	3	2	8	1	2	0	1	1	7	22	39	6
6	28	2	1	1	4	1	0	3	2	7	3	2	1	1	1	6	16	167	1
6	38	1	1	2	3	1	0	2	1	5	2	3	1	0	1	4	22	167	1
6	39	2	1	2	3	1	0	1	1	3	2	2	1	0	1	2	12	167	1
6	43	1	1	1	2	1	0	1	2	7	3	2	0	1	1	6	11	42	6
6	47	1	1	2	2	1	0	1	1	4	3	2	1	0	1	3	12	167	1
6	56	1	1	2	1	1	0	1	1	4	3	2	1	0	1	3	17	195	1

Annexure IV (Master chart) part 2: Household contacts details (n= 502)

Index case number	Age in years	Gender	Occupation	Literacy status	Marital status	Pregnant	Relation to the index case	Sleep location	Symptoms	Past history	Bag scar	Duration of cigarette smoking	Duration of alcohol intake	Duration of chewing tobacco	Diet	Duration of TPT in the past	Outcome of the TPT in past	Details of treatment for any other diseases	Duration between index case diagnosis and TPT initiation in the HHC	Support of treatment supervisor	Counselling regarding treatment duration	Counselling regarding side effects of drugs	IBOI	Sputum microscopy	Result	Months of follow-up	Total treatment duration in days	Total tablets consumed	Number of discontinuation periods	Duration of discontinuation	Reasons for discontinuation	Investigations	Result	Treatment outcome
1	45	1	1	4	1	0	4	1	0	0	1	0	0	0	2	0	0	0	18	1	1	1	27.2	3	2	18	188	161	4	27	11	0	0	1
1	44	2	2	2	1	0	4	2	0	0	1	0	0	0	2	0	0	0	17	1	1	1	25.4	3	2	18	187	158	3	29	7	0	0	1
1	20	1	2	3	2	0	2	2	0	0	1	0	0	0	2	0	0	0	18	1	1	1	26	3	2	18	190	160	4	30	7	0	0	1
2	34	2	2	2	1	0	4	2	0	0	1	0	0	0	2	0	0	0	20	1	1	1	27	3	2	18	190	167	3	23	13	0	0	1
2	36	1	1	4	1	0	4	2	0	0	1	0	0	0	2	0	0	0	21	1	1	1	26.5	3	2	18	188	162	4	26	11	0	0	1
2	55	1	2	1	4	0	5	2	0	9	1	20	20	0	2	0	0	4	20	1	1	1	22.4	3	2	18	200	160	7	40	1	0	0	1
3	12	1	2	3	2	0	3	2	0	0	1	0	0	0	2	0	0	0	18	1	1	1	20	3	2	18	189	161	3	28	7	0	0	1
3	40	1	1	3	1	0	4	2	0	0	1	0	0	0	2	0	0	0	18	1	1	1	26	3	2	18	179	168	4	11	13	0	0	1
3	40	2	1	4	1	0	4	2	0	0	1	0	0	0	2	0	0	0	17	1	1	1	27	3	2	18	188	167	4	21	11	0	0	1
3	15	1	2	3	2	0	3	2	0	0	1	0	0	0	2	0	0	0	18	1	1	1	21	3	2	18	190	162	3	28	7	0	0	1
3	17	1	2	3	2	0	3	2	0	0	1	0	0	0	2	0	0	0	18	1	1	1	22	3	2	18	190	162	3	28	7	0	0	1
4	44	1	1	4	1	0	4	2	0	0	1	0	0	0	2	0	0	0	16	1	1	1	27	3	2	18	190	170	3	20	11	0	0	1
4	38	2	2	2	1	0	4	2	0	0	1	0	0	0	2	0	0	0	16	1	1	1	25.5	3	2	18	188	167	3	21	13	0	0	1
4	17	1	2	3	2	0	3	2	0	0	1	0	0	0	2	0	0	0	16	1	1	1	23	3	2	18	188	170	3	18	7	0	0	1
5	26	1	1	4	1	0	1	1	0	0	1	0	0	0	15	1	0	0	15	1	1	1	25.7	3	2	18	190	178	3	12	11	0	0	1
6	32	2	1	4	1	0	1	1	0	0	1	0	0	0	2	0	0	0	18	1	1	1	26	3	2	18	189	171	4	18	11	0	0	1
6	11	2	2	2	2	0	2	2	0	0	1	0	0	0	2	0	0	0	18	1	1	1	19	3	2	18	187	170	3	17	13	0	0	1
6	52	1	1	3	1	0	4	3	0	9	1	20	20	0	2	0	0	4	18	1	1	1	27	3	2	18	188	168	2	20	1	0	0	1
6	48	2	2	1	1	0	4	3	0	9	1	0	0	15	2	0	0	4	18	1	1	1	26.8	3	2	18	174	166	2	8	3	5	2	1
7	63	2	2	2	1	0	5	3	1	9	1	0	0	20	2	0	0	4	17	1	1	1	24	1	2	18	189	167	7	22	1	0	0	1
7	74	1	2	2	1	0	5	3	1	9	1	20	20	0	2	0	0	4	17	1	1	1	22	1	2	18	189	176	6	13	4	0	0	1
7	36	1	1	5	1	0	1	1	0	0	1	0	0	0	2	0	0	0	18	1	1	1	26.7	3	2	18	187	156	4	31	11	0	0	1
7	12	2	2	2	2	0	2	2	0	0	1	0	0	0	2	0	0	0	16	1	1	1	21	3	2	18	185	167	5	18	7	0	0	1
7	14	1	2	2	2	0	2	2	0	0	1	0	0	0	2	0	0	0	18	1	1	1	22.3	3	2	18	184	166	5	18	7	0	0	1
8	42	1	1	3	1	0	1	1	0	0	1	0	0	0	2	0	0	0	19	1	1	1	27	3	2	18	190	172	5	18	11	0	0	1
8	19	2	2	3	2	0	2	2	0	0	1	0	0	0	2	0	0	0	18	1	1	1	24	3	2	18	189	177	3	12	13	0	0	1
8	17	1	2	3	2	0	2	2	0	0	1	0	0	0	2	0	0	0	19	1	1	1	25.2	3	2	18	178	161	2	17	7	0	0	1
9	75	1	2	1	1	0	4	3	0	9	1	0	0	0	2	0	0	4	17	1	1	1	26	3	2	18	165	131	7	34	1	7	1	4
9	72	2	2	1	1	0	4	3	0	9	1	15	15	0	2	0	0	4	17	1	1	1	25.3	3	2	18	182	148	7	34	1	0	0	1
9	37	2	2	2	1	0	1	1	0	0	1	0	0	0	2	0	0	0	16	1	1	1	24	3	2	18	189	170	4	19	13	0	0	1
9	19	2	2	4	2	0	2	2	0	0	1	0	0	0	2	0	0	0	15	1	1	1	22	3	2	18	190	172	5	18	7	0	0	1
10	43	2	1	4	1	0	1	1	0	0	1	0	0	0	2	0	0	0	17	1	1	1	27	3	2	18	189	170	4	19	11	0	0	1
10	22	1	2	4	2	0	2	2	0	0	1	0	0	0	16	1	0	0	16	1	1	1	25.6	3	2	18	185	167	3	18	7	0	0	1
10	62	1	2	1	4	0	4	3	3	9	1	20	20	0	2	0	0	4	15	1	1	1	21	3	2	18	199	156	7	43	13	0	0	1
11	59	2	2	1	1	0	1	1	0	9	1	0	0	0	2	0	0	4	18	1	1	1	23	3	2	18	200	160	6	40	1	0	0	1
11	38	1	1	4	1	0	2	3	0	0	1	0	0	0	2	0	0	0	17	1	1	1	26.3	3	2	18	189	177	3	12	11	0	0	1
11	36	2	1	3	1	0	5	3	0	0	1	0	0	0	2	0	0	0	18	1	1	1	25.7	3	2	18	188	172	2	16	13	0	0	1
11	14	2	2	3	2	0	5	3	0	0	1	0	0	0	2	0	0	0	18	1	1	1	22	3	2	18	188	177	3	11	7	0	0	1
11	12	2	2	3	2	0	5	3	0	0	1	0	0	0	2	0	0	0	17	1	1	1	22.2	3	2	18	187	178	3	9	7	0	0	1
12	43	1	1	4	1	0	2	3	0	0	1	0	0	0	2	0	0	0	19	1	1	1	26.2	3	2	18	189	177	4	12	11	0	0	1
12	40	2	1	3	1	0	5	3	0	0	1	0	0	0	2	0	0	0	19	1	1	1	25.3	3	2	18	190	167	3	23	13	0	0	1
12	61	2	2	1	1	0	1	1	0	9	1	0	0	0	2	0	0	4	19	1	1	1	22	3	2	18	200	166	7	34	1	0	0	1
12	19	1	2	3	2	0	5	3	0	0	1	0	0	0	2	0	0	0	19	1	1	1	23	3	2	18	188	156	2	32	7	0	0	1
12	15	2	2	3	2	0	5	3	0	0	1	0	0	0	2	0	0	0	19	1	1	1	21	3	2	18	187	176	3	11	7	0	0	1
13	44	1	1	4	1	0	2	3	0	0	1	0	0	0	2	0	0	0	18	1	1	1	26	3	2	18	188	177	1	11	13	0	0	1
13	42	2	2	2	1	0	5	3	0	0	1	0	0	0	2	0	0	0	18	1	1	1	24.7	3	2	18	189	172	2	17	13	0	0	1
14	68	2	2	1	1	0	1	1	0	9	1	0	0	10	2	0	0	4	15	1	1	1	21	3	2	18	200	160	7	40	13	0	0	1
14	41	1	1	4	1	0	2	3	0	1	1	0	0	0	2	0	0	1	15	1	1	1	25.6	3	2	18	190	170	3	20	11	0	0	1
14	40	2	2	2	1	0	5	3	0	0	1	0	0	0	2	0	0	0	16	1	1	1	24.4	3	2	18	188	172	4	16	1	0	0	1
15	41	1	1	3	4	0	2	2	0	0	1	0	0	0	2	0	0	0	18	1	1	1	26.2	3	2	18	190	177	4	13	11	0	0	1
15	64	2	2	1	1	0	1	1	8	9	1	0	0	0	2	0	0	4	18	1	1	1	23	3	2	18	198	167	5	31	1	0	0	1
16	95	2	2	2	1	0	5	3	0	2	1	0	0	0	2	0	0	0	2	0	1	1	25	3	2	17	190	176	5	14	13	0	0	1
16	47	1	1	4	1	0	4	2	0	0	1	0	0	0	2	0	0	0	17	1	1	1	26.4	3	2	17	177	167	3	10	11	0	0	1
16	42																																	

21	13	1	2	2	2	0	2	2	0	0	1	0	0	0	2	0	0	0	17	1	1	1	21.3	3	2	17	186	158	5	28	7	0	0	1
22	33	1	1	3	1	0	1	1	0	0	1	0	0	0	2	0	0	0	16	1	1	1	25.5	3	2	17	189	170	4	19	11	0	0	1
22	8	1	2	2	2	0	2	2	0	0	1	0	0	0	2	0	0	0	16	1	1	1	15.3	3	2	17	176	156	3	20	7	0	0	1
22	7	1	2	2	2	0	2	2	0	0	1	0	0	0	2	0	0	0	16	1	1	1	17.4	3	2	17	177	150	2	27	7	0	0	1
23	32	2	1	3	1	0	1	1	0	0	1	0	0	0	2	0	0	0	18	1	1	1	27	3	2	17	188	167	3	21	13	0	0	1
23	10	2	2	2	2	0	2	2	0	0	1	0	0	0	2	0	0	0	18	1	1	1	19	3	2	17	190	156	4	34	7	0	0	1
23	61	1	2	2	2	1	0	4	3	4	9	1	20	20	2	0	0	4	18	1	1	1	25.5	3	2	17	200	134	7	66	14	2	0	2
23	60	2	2	2	2	1	0	4	3	0	9	1	0	0	20	2	0	0	18	1	1	1	24	3	2	17	190	132	7	58	14	1	0	1
24	34	1	1	4	1	0	1	1	0	0	1	0	0	0	24	0	0	0	18	1	1	1	26.1	3	2	17	189	167	3	22	7	0	0	1
25	32	2	1	4	1	1	1	2	0	0	1	0	0	0	2	0	0	0	16	1	1	1	25	3	2	17	188	167	3	21	13	0	0	1
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131	62	2	2	1	1	0	5	3	0	9	1	0	0	0	2	0	0	4	13	1	1	1	22	3	2	15	187	172	3	15	13	0	0	1	
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139	16	2	2	2	2	0	1	3	0	0	1	0	0	0																					