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Original Research Article

A PROSPECTIVE STUDY TO DISCERN FACTORS AFFECTING SUCCESSFUL TUBERCULOSIS TREATMENT OUTCOME AMONG NEW PULMONARY DS-TB PATIENTS

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ABSTRACT

Background: Tuberculosis, which is a top infectious killer disease, is a global health concern owing to nearly one third of the global population being infected with mycobacterium tuberculosis and at a risk of developing the disease. India ranks first among the world's high burden tuberculosis (TB) countries with 26% of global case burden. **Objectives:** To prospectively follow newly diagnosed drug sensitive pulmonary tuberculosis cases under NTEP till their treatment outcome.

Materials and Methods: A community based prospective study is conducted in sarsawa block, Saharanpur district. The study was conducted over a period of 12 months. All drug sensitive TB patients registered in selected TU of block Sarsawa from October to December 2023 were included in the study.

Results: The treatment success rate among cured and treatment completed were found more than 87% and treatment failure rate was1%. Only 1% patients who were in study sample was not evaluated. Out of total study participants 6% were died during treatment.

Conclusion: Treatment adherence factors, knowledge and awareness about tuberculosis transmission plays important role for the successful treatment outcome.

Keywords: New sputum smear positive, drug sensitive TB, Pulmonary, TU, NTEP.

INTRODUCTION

One of the most dangerous infections that causes the most morbidity and mortality worldwide is tuberculosis. The global end TB plan has been put into practice to lower tuberculosis-related mortality, morbidity, and catastrophic costs; yet, the progress made to meet these goals has been sluggish and intimidating.[1]

India contributes 2.77 million (27%) of the global tuberculosis burden, accounting India's tuberculosis epidemic the largest in the world. Discontinuation of the TB programs due to emergence of Covid-19 led to the largest drop in tuberculosis notifications in India as compared to any country globally.[2]

With a strong worldwide commitment to eradicate the TB pandemic, the WHO End TB strategy aims to reduce mortality and incidence by 95% and 90%, respectively, by 2035, while preserving zero catastrophic costs for TB-affected families compared to the baseline of 2015. The Sustainable Development Goals (SDG) on the Path to End TB aim to reduce TB-related mortality by 90% and incidence by 80% by 2030, with no catastrophic costs to families impacted by tuberculosis. At the 2018 World End TB Summit, India pledged to meet the SDG goal of TB elimination five years ahead of schedule, or by 2025.[3]

Because tubercular infections are so prevalent, there is an urgent need for efficient methods to manage and

eradicate the illness. As part of India's national strategic plan to eliminate tuberculosis, active case finding (ACF) is a proactive strategy that involves systematic screening of the population through house-to-house visits by medical personnel.[4]

A 6 months standard short course of therapy for all categories of drug-sensitive tuberculosis includes two phases that is intensive phase for two months contains four medications (HRZE), namely Isoniazid (H), Rifampicin (R), Pyrazinamide (Z), and Ethambutol (E) at doses of 75/150/400/275 mg and continuation phase for four months of three medications, namely HRE at doses of 75/150/275 mg. This standard treatment protocol depends on fixed-dose combinations (FDCs) in which quantity of tablets calculated on patient's weight band. This treatment provided to all patients free of cost throughout the treatment period.[5]

Through the execution of its National Strategic Plan (NSP)-India 2017–2025, the Indian government intends to "End TB." By 2025, ambitious goals have been established for successful treatment outcomes: 75% for DR-TB and 92% for drug-sensitive TB. In India, only 79% of patients with DS-TB and 46% of patients with DR-TB received good treatment outcomes in 2017. Free TB diagnostic and treatment services are offered in India via the National TB Elimination Program (NTEP), formerly known as the Revised National Tuberculosis Control Program (RNTCP). The Nikshay platform (Ni- means End, Kshay means TB) is a web-enabled tool that was introduced by the Indian government in 2012 to help with TB patient monitoring throughout the country. Notification of all TB patients who were diagnosed or started on treatment in the Nikshay was required of all public and private health facilities. Poshan Abhiyan, a direct benefit cash transfer of ₹500 per month to patients undergoing treatment, was introduced by the NTEP in 2018 to help patients with their nutritional needs. Death, loss to follow-up, and treatment failure were all considered unfavorable or poor TB treatment results.[6]

Tuberculosis has been a prevalent infectious disease in our country claiming many lives and devouring many families in its wake. Though the efforts to control the disease have evolved from time to time starting from isolation in TB sanatorium to domiciliary treatment and directly observed short course treatment strategies has been introduced because of longer treatment duration patients and his/her family has to be committed for the cure of the disease along with the community to replicate the desirable outcome as per the national programme. Hence, present study is conducted to explore factors influencing successful TB treatment outcome.

MATERIALS AND METHODS

This community based prospective study was conducted in the Sarsawa block Saharanpur catchment area of Community Health Centre Sarsawa which is the RHTC attached to department of community medicine, Government Medical College, Saharanpur among all the new drug sensitive pulmonary patients registered for TB treatment under NTEP during the study period matching the inclusion and exclusion criteria was included in the study. Duration of study was from o1/10/2023 to 31/03/2024. The protocol of thesis was approved by the Institutional Ethical Committee (IEC/36-23/06/2023).

Sample Size: All the drug sensitive pulmonary TB patients registered in the selected TU of block Sarsawa from o1/10/2023 to 31/03/2024 was included in the study and were followed up till their treatment outcome had given.

Sampling Technique: No sampling techinque was employed and all the newly diagnosed pulmonary drug sensitive tuberculosis cases matching inclusion and exclusion criteria registered during the period mentioned above were included in the study.

Inclusion Criteria

1. Site of disease were Pulmonary.
2. Patients were drug sensitive TB patients.
3. Patients were belonged the age group of between 18 years and above 60 years.
4. Patients were resister in TU, block Sarsawa, Saharanpur, U.P.
5. Patients had given consent to participate in the study.

Exclusion Criteria

1. Patients were not initiated on treatment.
2. Seriously ill or bed ridden patients.
3. Patients who had not given consent to participate in the study.

Study Tool: Data will be collected using semi structured schedule by visiting the patient's home after treatment initiation. The patients will be followed up telephonically every fortnight till their treatment outcome is given. Additionally, monthly follow up of patient's record will be done at the treatment facility.

Data Entry and Statistical Analysis: Data collected was entered into excel sheet and analysed using the EpiInfo v 7.2.5

Tools of data collection:

1) Measuring tape made of non-stretchable steel which measures height to the nearest 0.1 centimetre.
2) Electronic weighing scale with capacity up to 150 kg which measures weight to the nearest 100 grams.
3) Glucometer for measurement of blood sugar.
4) Aneroid sphygmomanometer for measurement of blood pressure.
5) Pre-designed, pre-tested, semi-structured, self-administered questionnaire was used.
6) Before administering the questionnaire to study participants, the questionnaire was pretested on 50 elderly participants and changes have been made accordingly.

Statistical Analysis

Data was entered and analyzed using MS Excel and EPI.info 7.2.5. Both descriptive and inferential statistics were used. Participants baseline characteristics were presented as frequencies and percentages. Categorical variables between the groups were compared using Chi square test and Fisher's exact test. All statistical analysis was carried out at 5% level of significance and p value < 0.05 was considered as statistically significant.

RESULTS

The minimum and maximum age were 18 years and above. Majority of participants were in the age group of 46-60 years 31 (30%) followed by 18-30 years 29 (28%), 31-45 years 27 (26%), and above 60 years were 16 (16%). This shows that representation of participants in the study sample was higher in the age group of 46-60 years followed by 18-30 years, 31-45 years and above 60 years respectively. Out of 103 participants, 37(36%) were female and 66(64%) were male. This shows that representation of males was higher in the study sample compared to females.

This shows the respondents belong to SC community were 54 (52%) followed by OBC 41 (40%) and General 8 (8%) respectively. This indicated that representation of SC community was higher in the study sample than other backward class (OBC) and general.

Out of 103 respondents, 49(48%) were belongs to nuclear family and 54 (52%) belongs to joint family. This indicated that the representation of joint families was higher in the study sample than the nuclear families.

Out of 103 participants, 60 (58%) were Hindus and 43 (42 %) were Muslims. This indicated that Hindus were slightly more represented in the study sample compared to Muslims.

Out of 103 participants, 43 (42%) were Unemployed followed by 26 (25%) were doing their own business while 18 (17%) were labourer and 16 (16%) were doing their private services. This indicated that majority of the participants were Unemployed followed by those engaged in their Own Business, Laborers and few were doing their private services.

Out of 103 participants, 36 (35%) were illiterate followed by 27 (26%) were completed primary education, 21 (20%) high school, 18 (17%) intermediate and only 1 (1%) were completed graduation respectively. This indicated that majority of participants in the study sample were Illiterate.

Out of 103 participants, 56 (54%) were in lower middle-income class followed by 23 (22%) to the lower class, 20 (19%) to the middle class and 4 ((4%) belongs to the upper middle class. This distribution showed that lower middle class was the most represented group in the study sample.

Out of 103 participants the majority 58 (56%) of families have between 8 and 10 members, which suggests that a relatively larger family size is common. Families with more than 11 members make up 22% of the sample, while the smallest group (5–7 members) accounts for 21%. This distribution showed that family size with 8-10 members were most represented group in the study sample.

Table 1: Distribution based on weight band of the participants

Weight Band Category (kg)	Frequency (n)	Percentage (%)
25-34	6	6 %
35-49	76	74 %
50-64	18	17 %
65 and above	3	3 %
Grand Total	**103**	**100%**

Out of 103 participants, the most common weight range were 35-49, which accounts for nearly half 76 (45%) of the sample. The next most frequent category was 50–64, comprising 18 (17%) of the participants. Very few subjects fall into the extreme ranges: only 6 (6%) in the lowest range (25–34) and only 1 (1%) above 75. This indicated that the majority of the participants in the study sample had 35- 49 weight band category. This indicated that majority of the participants in the study sample were in 35-49 weight band category.

Table 2: Distribution based on body mass index (BMI) of the participants

BMI	Frequency	Percentage
<18.5	87	84%
18.5-24.9	14	14%
25 to 29.9	2	2%
30 or more	0	0%
Grand Total	**103**	**100%**

Out of 103 participants majority of the study subjects 87 (84%) were underweight followed by 14 (14%) have normal BMI while only 2 (2%) were overweight and no one were in obese category. This indicated that majority of participants were underweight in the study sample.

Out of 103 participants 94 (91%) do not have diabetes mellitus while 9 (9%) are diagnosed with diabetes mellitus. This indicated that majority of the participants were non-Diabetic while very few were suffered from Diabetes Mellitus.

Out of 103 participants 103 (100%) were non-reactive for HIV. This indicated that all the participants in the study sample were HIV negative.
Out of 103 participants, 43 (42%) has Haemoglobin levels between 10 and 13 g/dL followed by 38(37%) has Haemoglobin levels between 7 and 10 g/dL and only 22 (21%) have Haemoglobin levels greater than 13 g/dL. This indicated that majority of participants in the study sample were mild Anaemic and moderate Anaemic while very few were showing normal Haemoglobin level.
Out of 103 participants, 56 (54%) were chewing tobacco and 47 (46%) not chewing the Tobacco. This indicated that majority of the participants in the study sample were chewing the Tobacco.

Table 3: Distribution based on substance abuse by the participants

Substance Abuse	Frequency (n)	Frequency (%)
Tobacco	34	33 %
Alcohol	3	3 %
Both	22	21 %
No	44	43 %
Grand Total	**103**	**100 %**

Out of 103 participants, 59 individuals 34(33%), 3(3%) and 22 (21%) use at least one substance respectively. Among substance users, the most common category was tobacco only 34 (33%) individuals, followed by those using both tobacco and alcohol 22 (21%) individuals. Alcohol use alone is relatively rare, with only 3(3%) individuals. The largest group is those not engaged in substance abuse 44(43%) individuals. This indicated that majority of the participants in the study sample were tobacco users only.

Out of 103 participants majority 78 (76%) do not use alcohol and nearly one in four individuals 25 (24%) reported using alcohol. This indicated that majority of the participants in the study sample had not consumed alcohol.
Out of 103 participants, 66 (64%) were using alcohol and 37 (36%) were non-smokers. This indicated that majority of the participants in the study sample were smokers.

Table 4: Distribution based on treatment outcome of the participants

Treatment Outcome	Frequency (n)	Percentage (%)
Cured	67	65%
Died	6	6%
Not Available	3	3%
Not evaluated	1	1%
Treatment complete	23	22%
Treatment regimen changed	2	2%
Treatment failure	1	1%
Grand Total	**103**	**100%**

Out of 103 participants, 67 (65%) were reported as cured, 23 (22%) have completed treatment, 6 (6%) patients died during treatment, 3 (3%) patients' outcomes not available while 2 (2%) had their treatment regimen changed, 1 (1%) was not evaluated for the outcome and 1 (1%) experienced treatment failure. This indicated that majority of the participants in the study sample were reported as cured and treatment completed.

Table 5: Candidate Predictors

Candidate predictors		Frequency	Percentage (%)
Previous tb history	Yes	0	0.0
	No	130	100
Cavitation on x- ray	Yes	3	2.3
	No	127	97.7
Naat done	Yes	130	100
HIV test result	Negative	130	100
Diabetes	Yes	5	3.8
	No	125	96.2
Haemoglobin			
Tobacco use	Yes	75	57.7
	No	55	42.3
Use of alcohol	Yes	26	20
	No	104	80
Drug use	Yes	2	1.5
	No	128	98.5
Smoking	Yes	85	65.4
	No	45	34.6
Indoor air pollution	Yes	0	0.0
	No	130	100

This table presented the candidate predictors in study sample showing the frequency and percentage of people engaging in various habits like Tobacco use, Alcohol consumption, Drug use, Smoking, and exposure to Indoor air pollution among 130 participants out of that All 130 individuals (100%) had no past TB history, 3 individuals (2.3%) showed cavitation on their chest X-ray, 127 individuals (97.7%) had no cavitation on X-ray, All 130 individuals (100%) underwent NAAT testing, a molecular test for TB diagnosis, All 130 individuals (100%) tested negative for HIV, 5 individuals (3.8%) had diabetes, a known risk factor for TB,125 individuals (96.2%) were non-diabetic, 75 people (57.7%) reported using tobacco,55 people (42.3%) do not use tobacco, 26 people (20%) reported consuming alcohol, 104 people (80%) do not consume alcohol. This suggests that alcohol consumption is less common in the group surveyed. 2 people (1.5%) reported using drugs, 128 people (98.5%) do not use drugs, drug use is very low among the respondents. 85 people (65.4%) reported being smokers. 45 people (34.6%) do not smoke. This shows that smoking is quite prevalent, with nearly two-thirds of respondents identifying as smokers, 0 people (0.0%) reported exposure to indoor air pollution, 130 people (100%) do not experience indoor air pollution, this suggests that all respondents have a clean indoor environment without pollution.

DISCUSSION

In present study, majority of the participants 56 (54%) were in the age group of 18-45 years followed by 31(30%) in the age group of 46-60 years and 16 (16%) in the age group of >60 years. Sreenivasulu T et al,[7] also reported that majority (50%) of the participants were in the age group of 21-40 years followed by 28.3% were in the age group of 45-60 years. This indicates that young adult to middle age group is more prone to TB disease.

In present study majority of participants 64% were male and 36% were female. Singh, et al,[8] in his study Haridwar district, Uttarakhand found that 67% participants were male and 33% were female.

In present study 52% participants belongs to scheduled caste (SC) followed by 40% other back ward (OBC) and 8% were general in our study sample. Rajnish et al A,[9] cross- sectional study was conducted at DOTS centre of Rajendra institute of medical sciences Ranchi in which they found in his study that scheduled caste (SC) were 2.1%, OBCs and general were 29.4%.

In present study 52% belonged to joint family and 48% belonged to nuclear family in the study sample. Umayorubhagom et al,[10] in his study also found that join family were 52.33% and 47.67% were belongs to nuclear family. This indicated that culture of living as joint family is more common in India as compared to nuclear or third generation family.

Hindus were 58% and Muslims were 42%. Sumana, et al,[11] in her study found that Hindus were 73.67% and Muslims were 22.7% in her study. Rajnish et al,[9] were also found in their study that 37.2% Hindus and 14% were Muslims. This shows that Hindus are more common representative in both the studies as compared to Muslims.

Occupation of the participants in the study sample found that majority 42% of the participants were unemployed followed by 25% self-employed, 16% were doing private service and 17% were engaged as labourer. Rajavardhana T. et al,[12] A cross-sectional study was conducted in Government General Hospital, Ananthapuramu, and Bathalapalli, Chennai, Tamil Nadu, India also reported that 72.3% were unemployed and 27.6% were employed. This Employment plays a crucial role in the well-being of tuberculosis (TB) patients in India, affecting their treatment, recovery, and overall quality of life.

Majority 35% were Illiterate followed by 26% received primary education, 20% till high school and 18% had received education till intermediate and above. Fatehpuria CM et al13 found in his study that 38.3% were illiterate followed by 22% taking primary education, 21.2% middle class and 12.9% were in higher secondary.

54% were lower middle class followed by 22% lower class, 19% middle class and only 4% belonged to the upper class as per modified BG Prasad Socio-economic Scale (January 2024). In a study conducted by Saleem M et al,[14] showed that 38.9% belonged to middle class followed by 42.2% of middle class, 7.8% were lower middle class and only 2.2% belonged to lower class.

Families with more than 11 members were 22% of the sample, while the smallest group 5–7 members accounts for 21%. Fatehpuria CM et13 al reported that 51.24% families had 5-8 members, 24.52% had >8 members in their family and 24.24% families had <4 members in their family. This indicated that in India, large family size plays a significant role in TB transmission, treatment adherence and economic burden. Overcrowding and close contact with infected individuals have Increased Risk of TB Transmission.

Majority 74% of the participants were in 35-49 kg weight band followed by 17% were in 50-64 kg, 6% were in 25-34 kg and only 3% were in above 60 kg weight band. Anand P et al,[14] in his study conducted in Tamil Nadu, South India. also showing that 60.2% patients were in <45 kg weight band and 39.2% were in > 45 kg weight band.

84% participants have their BMI <18.5 classified as underweight followed by 14% have BMI 18.5- 24.9 Normal, only 2% have their BMI 25-29.9% classified as overweight and no one had their BMI 30 or more.

91% were nondiabetic and only 9% had diabetes mellitus. Velayutham B et al,[15] revealed that 81% were nondiabetic and 19% were diabetic in her study indicated that most of the participants were nondiabetic in both the study. Vyawahare C et al,[15]

also found that 92.59% were non diabetic and 7.41% were diabetic in the study sample. This signifies that most of the participants were nondiabetic in these study samples which is concurrent finding with current study.

All the participants (100%) were non-reactive for HIV, Velayutham B et al,[15] revealed that 96% of the study participants were non-reactive for HIV testing while only 3% were reactive for HIV test. In HIV patients there is increased risk of co-infections which increases the risk of drug-resistant TB, treatment failure, and mortality.

37% have their haemoglobin level between 7-10 mg/dl classify as moderate anaemic, 42% have 10-13 gm/dl haemoglobin categorise as mild anaemic and 21% have their haemoglobin level were >13 gm/dl.

54% were chewing tobacco while 46% were not using tobacco. Vyawahare C et al,[15] also shows in his study that 91.53% were not using tobacco while 11.64% were chewing tobacco. Smoking damages the lungs and weakens local immunity, making TB infection more likely. Smoking is also linked to lower treatment adherence and reduced effectiveness of TB medications.

3% were using alcohol while 21% using both the substance like tobacco and alcohol, and 43% were not showing any substance abuse. The substance abuse can suppress the immune system, making TB infection and disease progression more likely. Substance abuse is linked to poor adherence to TB therapy.

76% not using alcohol while 24% participants were using alcohol during the course of treatment. Veerakumar AM at al,[16] revealed that 68.5% were not consuming alcohol and 31.5% were consuming alcohol in the study sample. Vyawahare C at al,[15] also shows in the study that 94.71% were not consuming alcohol while 5.29% were consuming alcohol. Consumption of alcohol weakens the immune system and making tubercular patients more prone for infections and disease progression. Alcohol also causes liver damage which exacerbate the liver damaging effects on tubercular medications like Isoniazid and Rifampicin.

64% were smokers while 36% of the participants were non- smokers. Velayutham B et al,[15] showing that 52% were non-smokers and 48% were smokers in their study sample. Thamineni R et al,[12] also shows that in study sample 70.6% were non- smokers while 29.3% were smokers. This indicated that majority of the participants were non-smokers.

65% were classified as cured followed by 22% had treatment completed, 6% had their outcome was dead, 2% have treatment regimen changed, 1% have treatment failure 1% were not evaluated and outcome of 3% were not available. Bagga RV et al,[17] revealed about the treatment outcome of tubercular patients that 80% were reported as cured followed by 42.1% reported as treatment completed,2.7% were died and 1,4% were showing treatment failure.

CONCLUSION

While tuberculosis remains a serious global health issue, it is preventable and curable with timely intervention and collective action. Governments, healthcare professionals, researchers, and individuals must work together to ensure proper treatment access, reduce stigma, and promote TB awareness. With sustained efforts, it is possible to significantly reduce the burden of TB and move towards a future free from this devastating disease.

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