Diagnosis and Management of Tuberculosis

Chapter 4

Treatment response of retreatment category tribal Pulmonary Tuberculosis patients lived in Eastern India

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Abstract

Objective: The study was conducted to assess the treatment outcome of different category retreatment cases with the aim of finding out the important predictors of unfavorable outcomes.

Methodology: This hospital based prospective cohort study was conducted in three Tuberculosis unit (TU) of west Midnapore (a district of eastern India), covering mostly the tribal populated areas. Patients who were registered for Category II anti-tuberculosis treatment between 1st quarter 2013 (Jan to Mar) to 4th quarter 2013 (Oct to Dec), were considered as our study cohort and they were followed upto December 2014. The study was started with 177 patients but ultimately ended with 165 patients.

Results: Unfavorable outcome was observed among 24.8% patients. Among them mostly (51.2%) were defaulter, 22% were failure case and 26.8% patients died during treatment. Patients, who were minority by religion, were found 4 times more vulnerable for unfavorable outcome. Unfavorable outcome were found 7 times more common among retreatment TB cases who remain sputum positive after completion of initiation phase of category II treatment.

Conclusion: Programmatic approach should be specified to address the minority by religion population and to reduce the load of sputum positive cases after completion of initiation phase treatment by tracking them.

Keywords: tribal population; retreatment pulmonary TB case; sputum positive; prospective cohort study

1. Introduction

In Indian continent Tuberculosis (TB) is oldest communicable, fatal infectious disease that is deeply rooted among Indian population since 1500 BCE (well evident around 500 BCE literatures). History has evidence that many emperors died and many empire demolished due to this fatal disease in India [1,2]. Still India can't rid of from this curse.

1.1 Current situation

The World Health Organisation (WHO) statistics of 2015 reported that only in India Tuberculosis incidence is near to one fourth of global TB incidence (2.2 million cases of TB for India out of a global incidence of 9.6 million). Prevalence of TB was 2.5 million estimated in same year. But the burden of Tuberculosis infection is huge. About 40% people of India is carrying this micro-organism in their body. Most of them have latent infection rather than active manifestation. It indicates that number of susceptible population is vast in this country [3,4]. Globally 2–3 million deaths are reported annually out of more than 9.8 million new cases of active TB [5,6]. In 2014 [1], 78,000 retreatment pulmonary TB cases were registered in India, 70% were treated successfully and 8% were died [7].

After completion of standard first-line TB treatment patients who are failure, defaulter, or relapse, are grouped together as Category II cases and allocated for retreatment according to the World Health Organization (WHO). In India where individual drug susceptibility testing (DST) facilities are not universally scaled up still now, there patients are often treated with a standard retreatment regimen of first-line agents (a regimen that adds a single drug to the standard initial TB treatment regimen) [8]. Retreatment case's outcomes often are found poor as MDR-TB, especially in patients with treatment failure or default cases [9].

Though in late, but India realized to face the emergent problem immediately and launched Revised National Tuberculosis Control Programme (RNTCP) in 1997. After that, this programme gradually expanded across the country and in 2011, it achieved initial targets (71% new sputum positive case detection rate and 87% treatment success rate). So many programmatic errors, HIV-TB treatment issues, increasing number of Multi drug resistant TB cases are hindering the success over Tuberculosis [10].

Inappropriate implementation of the Revised National Tuberculosis Control Programme (RNTCP) causes precipitation of MDR-TB cases in the community. In this situation, India is not well equipped to prevent the propagation and dissemination of MDR-TB cases. So a new reemerging threat is slowly growing within the Indian population that may arise as a big challenge in future. MDR-TB is a man-made phenomenon-poor treatment, poor drugs and poor adherence lead to the development of MDR-TB [11].

1.2 Why we concern about tribal populations?

8.6% population of India belongs to tribal group and they are considered as an under privileged society due to lack of knowledge, poverty, ancient under developed culture, life style and behaviors. Prevalence of Tuberculosis among tribal population is varied in different studies. Beena Thomas et.al. estimated pooled TB prevalence among Indian Tribal Population (703 per 1 lakh) and that was significantly higher than estimated figure of TB prevalence of all over India (256 per 100,000) [12]. But Bhat J et al found no significant difference of TB prevalence among tribal and non tribal groups [13]. Most of the studies among tribal population in this field has been published on prevalence of the disease. Predictors of the disease or response of treatment among them got less attention in the research field.

The tribal populations of Eastern India are likely to live in particular discrete hard to reach geographic areas and always remain away from the light of civilization and often with poor access to the health care system. These factors make a communication barrier with all health care facilities and make them more vulnerable to develop drug resistant TB.

Smear +ve and –ve previously treated pulmonary TB cases are suspected as MDR-TB case according to Programmatic Management of Drug Resistant TB (PMDT) guideline. But in India where drug resistance TB diagnosis facilities are not available widely still now, there unfavorable outcomes of retreatment TB cases in the environment of poor RNTCP covered area (Tribal areas) can be suspected highly as the source of drug resistant TB. Unfavourable outcome of retreatment TB cases and poorly accessed health facility areas (Tribal area) both could be consider as common attributed factors for drug resistant TB [11].

In eastern India retreatment TB related research work among tribal population is very limited. In this background a study was conducted to assess the treatment outcome of different category retreatment cases with the aim of finding out the important predictors of unfavorable outcomes and enlighten the issues which are paid less importance.

2. Materials & methods

A prospective cohort study was conducted in three Tuberculosis units (TU) of west Midnapore (a district of eastern India), covering mostly the tribal populated areas. West Midnapore is a district of eastern India where 14.87% populations are belonging to tribal family and are living with their traditional tribal culture. In this rural district tuberculosis treatment services are provided from 11 TUs, 52 district microscopy centre, 119 peripheral health institute, 25 sputum collection centre and 945 DOT centers. 25% of TUs (3 TU) were purposively selected where tribal inhabitants are more.

Our study cohort included all the tribal people who were registered for Category II anti-

tuberculosis treatment between 1st quarter 2013 (Jan to Mar) to 4th quarter 2013 (Oct to Dec). They were followed up until their treatment was completed as per DOTS guideline that is December 2014. Patients, who had incomplete follow up data in register and who were transferred out during the treatment, were excluded from the study. All the data related to exposure and outcomes were collected from Tuberculosis unit's register and their follow up data were also tracked from same secondary data source.

Complete enumeration method was applied here. In the year of 2013, 478 retreatment cases were registered in those 3 TUs. Among them 37% (177) cases were belonging to tribal population. Tribal were identified, by observing the surname lists under the tribal caste with clarification from the General Administration, as and when necessary. The study was started with these 177 patients but ultimately ended with 165 patients, because 9 patients were excluded due to incompletion of data and 3 were transferred out during the treatment. (Figure 1).

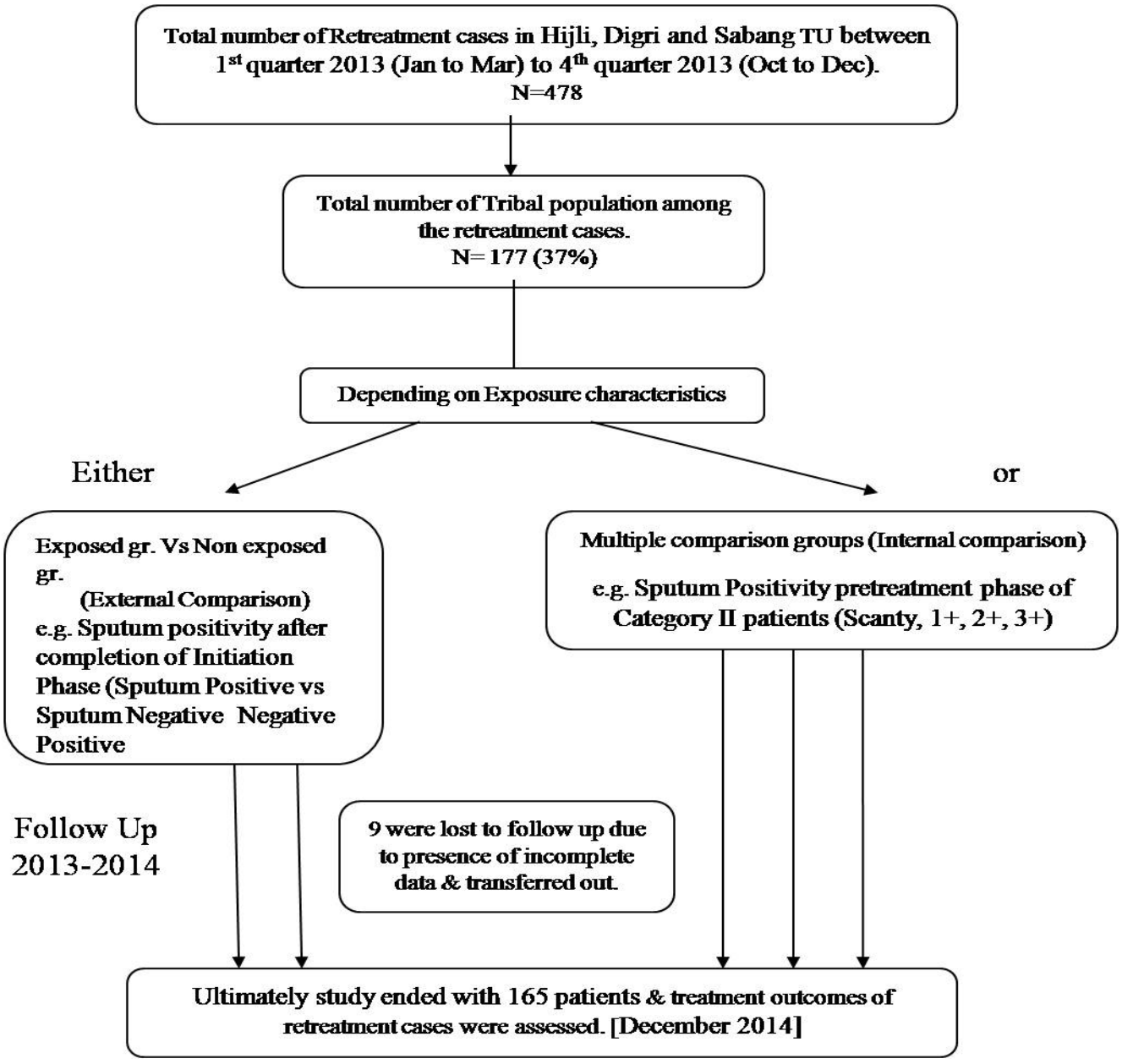

Figure 1: Schematic diagram showing the study design.

3. Operational definitions according to RNTCP guideline [14]:

3.1 Category of patients present among retreatment case cohort

Relapse: A TB patient who was declared cured or treatment completed by a physician and who reports back to the health facility and is now found to be sputum smear positive. *Treatment after default*: A patient, who has received treatment for TB for a month or more from any source and returns for treatment after having defaulted i.e., not taken anti-TB drugs consecutively for two months or more and found to be smear-positive. *Treatment failure*: Any TB patient who is smear-positive at 5 months or more after initiation of treatment. *Others*: A patient who does not fit into the any of the types mentioned above. The reasons for labeling a patient under this type must be specified in the Treatment card and TB Register.

3.2 Treatment outcome

3.2.1 Favourable outcome

Cured: Initially sputum smear positive patient who has completed treatment and had negative sputum smears on two occasions, one of which was at the end of the treatment. *Treatment completed*: Initially sputum smear positive patient who has completed treatment with negative smears at end of the intensive phase / two months in the continuation phase, but none at the end of the treatment is declared as treatment completed. Or initially sputum smear negative patient who has received full course of treatment and has not become smear positive at the end of the treatment.

3.2.2 Unfavourable outcome

Died: Patient who died during the course of treatment regardless of any cause. *Failure*: Any TB patient who is smear positive at five months or more after initiation of the treatment and not put on MDR-TB treatment. *Defaulted*: A Patient after treatment initiation has interrupted treatment consecutively for >2 months.

Patients were categorized according to following variables like age, gender, address, religion, type of category II patient (relapse, failure, treatment after default), level of sputum positivity. These variables were considered as exposure characteristics for this cohort.

Statistical analysis: Data were entered in Microsoft Excel worksheet (Microsoft, Redwoods, WA, USA) and were analyzed using IBM SPSS software, version 19.0 (Statistical Package for the Social Sciences Inc, Chicago, IL, USA) and Microsoft Excel. Chi square test was performed for bivariate analysis. Variables which were found statistically significant (p= 0.05) in bivariate analysis were considered for logistic regression model and adjusted odd ratio was assessed for predictor variables. Relative risk and attributed risk were also assessed for

significant predictors of unfavourable outcome.

4. Results

Baseline characteristics of the cohort: Among 165 tribal patients, 53.9% were belonging to adolescent and young adult group, 84.2% were male, 81.8% were Hindu and 69.7% were residing at rural community. Most of the cases of Category II patients were relapsed case (33.9%) and 29.7% cases were defaulter after preliminary treatment. In pretreatment period, most of the cases (31.5%) were 2+ sputum positive. After receiving initiation phase of category II treatment 9.7% remained sputum positive. Unfavorable outcome was observed among 24.8% patients. Among them mostly (51.2%) were defaulter, 22% were failure case and 26.8% patients died during treatment.

Bivariate analysis: As all the variables (exposure characteristics) were qualitative in nature, chi-square test/ Fisher exact test were applied to find out the association with treatment outcomes. The associations of unfavorable outcomes were found significantly more among adolescent and young adult patients (73.2%), treatment after default category patients (46.3%), patients who were 2+ & 3+ sputum positive at pretreatment phase (39% + 31.7% = 70.7%) and who were sputum positive after completion of initiation phase (75.6%). The chances of unfavorable outcomes were observed significantly more among minority by religion patients in comparison to favorable outcomes (34.1% vs 12.9%) (Table 1).

Table 1: Bivariate analysis between patient's profile and treatment outcome.

Patient's Profile	Favourable outcome N(%)	Unfavourable outcome N (%)	Chi-square test
Age			
Adolescent & Young Adult (11-40)	59 (47.6)	30 (73.2)	χ^2=10.066 df=2 p=0.007*
Middle age (41-60)	59 (47.6)	8 (19.5)	
Geriatric >60	6 (4.8)	3 (7.3)	
Gender			χ^2=0.052
Male	104 (83.9)	35 (85.4)	df=1
Female	20 (16.1)	6 (14.6)	p=0.82
Address			χ^2=0.028
Rural	86 (69.4)	29 (70.7)	df=1
Urban	38 (30.6)	12 (29.3)	p=0.868
Religion			χ^2=9.838
Hindu	108 (87.1)	27 (65.9)	df=2
Minority by religion	16 (12.9)	14 (34.1)	p=0.007*

Type of Category II patients **Treatment after Default** **Failure** **Relapse** **Transferred In** **Others**	 30 (24.2) 6 (4.8) 43 (34.7) 35 (28.2) 10 (8.1)	 19 (46.3) 5 (12.2) 13 (31.7) 2 (4.9) 2 (4.9)	χ^2=15.591 df=4 p=0.004*
Sputum Positivity pretreatment phase of Category II patients **Scanty** **1+** **2+** **3+**	 47 (37.9) 27 (21.8) 36 (29) 14 (11.3)	 3 (7.3) 9 (22) 16 (39) 13 (31.7)	χ^2=18.338 df=3 p=0.000*
Sputum positivity after completion of Initiation Phase **Negative** **Positive**	 118 (95.2) 6 (4.8)	 31 (75.6) 10 (24.4)	Fisher exact test p value= 0.001*

Among all types of unfavorable outcomes, defaulters were found as most common treatment outcome (51.2%). Defaulted treatment outcomes were observed mostly among adolescent and young adult patients (53.3%), minority by religion (71.5%) and treatment after default category II patients (52.6%). After completion of initiation phase 50% of the sputum positive patients completed their treatment period as failure cases. About half (46.1%) of the pretreatment phase (3+) sputum positive patients, died during category II treatment phase. (Table 2).

Table 2: Distribution of tribal patients according to the patient's profile and treatment outcome.

	Favourable outcome			**Un-favourable outcome**			
	Cured	**Treatment Completed**	**Total**	**Failure**	**Defaulted**	**Died**	**Total**
Age							
Adolescent & Young Adult (11-40)	41 (69.49)	18 (30.51)	59 (100)	6 (20)	16 (53.3)	8 (26.7)	30 (100)
Middle age (41-60)	38 (64.4)	21 (35.6)	59 (100)	2 (25)	3 (37.5)	3 (37.5)	8 (100)
Geriatric >60	3 (50)	3 (50)	6 (100)	1 (33.3)	2 (66.7)	0 (0)	3 (100)
Gender							
Male	71 (68.3)	33 (31.7)	104 (100)	8 (22.9)	17 (48.5)	10 (28.6)	35 (100)

Female	11 (55)	9 (45)	20 (100)	1 (16.7)	4 (66.6)	1 (16.7)	6 (100)
Address							
Rural	55 (64)	31 (36)	86 (100)	7 (24.1)	16 (55.2)	6 (20.7)	29 (100)
Urban	27 (71.1)	11 (28.9)	38 (100)	2 (16.6)	5 (41.7)	5 (41.7)	12 (100)
Religion							
Hindu	68 (63)	40 (37)	108 (100)	8 (29.6)	11 (40.6)	8 (29.6)	27 (100)
Minority by religion	14 (87.5)	2 (12.5)	16 (100)	1(7.1)	10 (71.5)	3 (21.4)	14 (100)
Types of Category II patient							
Treatment after Default	29 (96.7)	1(3.3)	30 (100)	3(15.8)	10 (52.6)	6 (31.6)	19 (100)
Failure	6 (100)	0 (0)	6 (100)	3(60)	2(40)	0 (0)	5 (100)
Relapse	36 (83.7)	7(16.3)	43 (100)	2(15.4)	7(53.8)	4(30.8)	13 (100)
Others	8(80)	2(20)	10 (100)	1(50)	1(50)	0(0)	2 (100)
Transferred In	3(8.6)	32(91.4)	35 (100)	0(0)	1(50)	1(50)	2 (100)
Sputum Positivity pretreatment phase of Category II patients							
Scanty	10 (21.3)	37 (78.7)	47 (100)	1 (33.3)	1 (33.3)	1 (33.3)	3 (100)
1+	25 (92.6)	2 (7.4)	27 (100)	1 (11.1)	6 (66.7)	2 (22.2)	9 (100)
2+	33 (91.7)	3 (8.3)	36 (100)	4 (25)	10 (62.5)	2 (12.5)	16 (100)
3+	14 (100)	0 (0)	14 (100)	3 (23.1)	4 (30.8)	6 (46.1)	13 (100)
Sputum positivity after completion of Initiation Phase							
Negative	77 (65.3)	41 (34.7)	118 (100)	4 (12.9)	19 (61.3)	8 (25.8)	31 (100)
Positive	5 (83.3)	1 (16.7)	6 (100)	5 (50)	2 (20)	3 (30)	10 (100)

Logistic regression: Factors which were found statistically significant in bivariate analysis were considered for logistic regression to measures the relationship between the categorical dependent variable (unfavorable outcome) and one or more independent variables. The logistic regression model was significant, as evident from omnibus chi-square test (P = 0.00). All the independent variables together can explain between 21.7 % to 32.1% variance of the dependent variable (unfavorable outcome), as evident from Cox & Snell and Nagelkerke R square. Regression model can correctly predict 91.9% of favorable outcome and 36.6% of unfavorable outcome. Overall, the model predicts 78.2% of the outcome correctly, as shown by classification table. Ultimately in logistic regression model, religion and sputum positivity after completion of initiation phase were predicted as the significant variable of unfavorable

outcome. Patients, who were minority by religion, were found 4 times more vulnerable for unfavorable outcome [Odd's Ratio = 4.1 (95% Confidence Interval = 1.6-10.8), P = 0.004]. Unfavorable outcome were found 7 times more common among retreatment TB cases who remain sputum positive after completion of initiation phase of category II treatment [Odd's Ratio = 6.9 (95% Confidence Interval=1.9-24.7), P=0.003] (Table 3).

Table 3: Logistic regression model for the predictors of unfavourable outcome

Omnibus Tests of Model Coefficients				
		Chi-square	df	Sig.
Step 1	Step	40.272	8	.000
	Block	40.272	8	.000
	Model	40.272	8	.000

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	144.747[a]	.217	.321

a. Estimation terminated at iteration number 6 because parameter estimates changed by less than .001.

Variables in the Equation									
		B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I.for EXP(B)	
								Lower	Upper
Step 1[a]	11. Age	-.014	.016	.723	1	.395	.986	.955	1.018
	2. Religion	1.415	.493	8.226	1	.004	4.115	1.565	10.821
	3. Type of Category II patients			6.099	4	.192			
	Treatment after Default(1)	1.416	.896	2.494	1	.114	4.120	.711	23.876
	Failure (2)	.985	1.080	.831	1	.362	2.678	.322	22.241
	Relapse (3)	.671	.898	.558	1	.455	1.955	.336	11.367
	Transferred in & Others(4)	-.529	1.226	.186	1	.666	.589	.053	6.515
	4. Sputum Positivity pretreatment phase of Category II patients	.358	.250	2.042	1	.153	1.430	.876	2.336
	5. Sputum positivity after completion of Initiation Phase	1.937	.649	8.920	1	.003	6.940	1.946	24.746
	Constant	-4.402	1.359	10.491	1	.001	.012		

a. Variable(s) entered on step 1: Age, Religion, Type of Category II patients, Sputum Positivity pretreatment phase of Category II patients, Sputum positivity after completion of Initiation Phase.

Classification Table[a]					
	Observed		Predicted		
			outcome		Percentage Correct
			.00	1.00	
Step 1	outcome	Favorable (0.00)	114	10	91.9
		Unfavorable (1.00)	26	15	36.6
	Overall Percentage				78.2

a. The cut value is .500

Scoring:

Religion: Hindu=0, Minority by religion=1; Type of Category II patients: Treatment after Default=0,

Failure=1, Relapse=2, Transferred in & Others=3; Sputum Positivity pretreatment phase of Category II patients: (Scanty & 1+) = 0, (2+&3+) =1; Sputum positivity after completion of Initiation Phase: negative=0, positive=1.

Relative risk and attributed risk: Relative risk and attributed risk were calculated for the significant predictors. Relative risk showed that patients, who had sputum positive after completion of initiation phase, had 2.98 times more risk than others for the development of unfavorable outcome. In case of minority by religion that risk was 2.35 times more than Hindu tribal. Attributed risk indicated that 66.4% of unfavorable outcome occurred due to failure of sputum conversion after initiation phase of treatment. Religion of retreatment cases attributed 57.4% cases of unfavorable outcome when they were belonging to minority by religion (Table 4).

Table 4: Relative risk and Attributed risk for significant predictors of unfavorable outcome

Predictors of unfavorable outcome	Relative risk	Attributed risk (%)
Religion	2.35	57.4
Sputum positivity after completion of Initiation Phase	2.98	66.4

5. Discussion

In the present study we have found 75.2% favourable outcome that is similar with the treatment success rate (71%) of India in retreatment TB cases [15].

Table 5: Comparison between different studies about treatment success rate among retreatment Tuberculosis cases

Study	Place of study	Population of study	Treatment Success rate
Our study, 2014	West Bengal, India	Tribal population	75.2%
Sevim T et al, 2002[16]	India	All type of relapse & defaulter cases	71.9%
Win A N et al, 2012[17]	Mayanmar	All type of retreatment cases	73%
Brahmapurkar KP[18]**, 2013**	Chattisgarh, India	All type of retreatment cases, mostly tribal patients	64.9%

Though the studies were conducted in different settings still it showed that treatment success rate among retreatment cases within India did not vary enough as well as in other Asian country (Mayanmar) also. But Brahmapurkar KP study conducted in tribal district of central India found lower success rate. It indicates that treatment success rate varies with tribal community. As treatment response of eastern India tribal retreatment patients was found comparable with overall performance of India.

Among the unfavourable outcomes more were defaulter (51.2%) that is also collaborate with the Vijay S et al (72.8%) & Vasudevan K et al (37.6%) study, but in our study, rate of defaulters were quite less than Vijay S et al study and quite higher than Vasudevan K et al study [19,20]. Though the rate of defaulters were varied widely within the India but in all studies it were counted as most common unfavourable outcome. More number of defaulters indicates the failure of programme implementation like poor coverage and lack of tracking activity of defaulters under the RNTCP. In the present study, unfavorable outcomes were found significantly more among adolescent and young adult patients (73.2%), minority by religion (26.8%), treatment after default category patients (46.3%), patients who were 2+ & 3+ sputum positive at pretreatment phase and who were sputum positive after completion of initiation phase. Vijay et al study found treatment after default category patients as potential defaulters/ unfavourable outcome that is also supported by our study findings. Both Vijay et al and Dandekar RH et al study found gender as significant predictors of overall unfavourable treatment outcome, but we did not find any significant relationship between gender and unfavourable treatment outcome [19,21]. We observed unfavourable outcome commonly among high grade sputum positive patients that is also collaborative with the Mukherjee A et al study observations. They also found unfavourable outcome most likely among treatment failure subgroup but we observed it more among treatment after default category patients (46.3%) [22].

Ultimately logistic regression model found that patients, who were minority by religion, were 4 times more vulnerable for unfavorable outcome [Odd's Ratio=4.1 (95% Confi-

dence Interval=1.6-10.8), P=0.004] and it was 7 times more common among retreatment TB cases who remain sputum positive after completion of initiation phase of category II treatment [Odd's Ratio = 6.9 (95% Confidence Interval = 1.9-24.7), P = 0.003]. This regression model can predict only 36.6% of unfavorable outcome correctly. Programmatic variables were not assessed in our study that can explain the low predictability of regression model. In spite of poor predicted ability of the regression model, it predicted two most important predictors of unfavourable outcome that should be intervened to improve the treatment outcome of retreatment TB cases.

In our study patients who were minority by religion they were more susceptible to unfavourable outcomes, but Dandekar RH found no significant relationship between them and no such observation was found in other studies also. It might be that minority among tribals were more hard to reach group due to their cultural and communication barrier. Sputum conversion rate in our study was 90.3% and that is quite higher than Vasudevan K et al study's observation (76.9%). Patients who remain sputum positive after completion of initiation phase of category II treatment they were found more susceptible to unfavourable outcome [OR=6.9] that is also suggested by Dooley KE et al study [OR=7.14] in Morocco [23]. In our study, although there was no such scope to measure drug sensitivity and resistance, it could be assume that more unfavourable outcome among unsuccessful sputum converted cases probably due to development of drug resistance. It might be single drug or multi drug resistance. If the MDR-TB diagnostics resources facility scaled up everywhere then the problem could be figure out more elaborately and results would be more evidence based. Kritski et al reported that unfavorable response to retreatment regimen was significantly associated with multidrug-resistant M *tuberculosis* infection [24].

Though the present study was not any comparison between tribal and non tribal population, its outcome were found more or less same as overall treatment outcome. Although poor living conditions, malnutrition, erroneous health assumptions and beliefs concerning TB, lack of resources and treatment by traditional healers increases the burden of TB among the tribal/indigenous population [25-27], but the treatment outcome is not significantly associated with ethnicity that was also observed in a previous study conducted by Chakrabarti S et al in West Bengal [27]. It indirectly indicates that programme failure related variables like lack of access to proper treatment, traditional and cultural barriers, lack of tracking of defaulters, etc. which were not addressed in previous study, were more important predictors than socio-demographic characteristics and it was felt by Chakrabarti et al. also [28]. That means unfavourable outcome among tribal population can be avoided, because it less depends on non modifiable factors like ethnicity.

6. Conclusion

This study was conducted among tribal population in assumption that unfavourable outcome will be found more prevalent among them. But the study results collaborated with the overall treatment outcome of India. In the end of the study patients who were minority by religion and who remained sputum positive after completion of initiation phase of treatment, were found more susceptible to unfavourable outcome. Programmatic approach should be specified to address the minority by religion population by breaking the communication barrier. Tracking of defaulters, early diagnosis of drug resistance cases by scaling up diagnostic facilities can reduce the load of sputum positive cases after completion of initiation phase treatment as well as unfavourable outcome also. The study concluded that tribal ethnicity does not affect retreatment case treatment outcome, but their religious belief have an impact on it. In future studies if the programme related variables could be addressed, more important predictors of retreatment cases outcome will be revealed.

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