

Evaluating the factors affecting the compliance of treatment adherence among tuberculosis patients of Haryana

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Introduction

Tuberculosis is an airborne disease caused by the Mycobacterium tuberculosis (M. tuberculosis). M. tuberculosis and seven very closely related mycobacterium species (M. bovis, M. africanum, M. microti, M. caprae, M. pinnipedii, M. canetti, and M. mungi) together comprise what is known as the Mycobacterium tuberculosis complex. Most, but not all of these species have been found to cause disease in humans. Tuberculosis can affect any organ in the body. Pulmonary tuberculosis is the most frequent site of involvement; extrapulmonary tuberculosis is less frequent. ^{1,2}

Anti-Tuberculosis medicines have been used for decades and strains that are resistant to one or more of the medicines have also been documented. Weak medical systems, inappropriate treatment that amplifies resistance patterns, and transmission in communities and facilities are the key factors contributing to the spread of resistant tuberculosis. Multidrug-resistant tuberculosis (MDR-TB) is a form of Tuberculosis caused by bacteria that do not respond to the 2 most effective first-line anti-TB drugs i.e., isoniazid and rifampicin. MDR-TB is treatable and curable by using second-line drugs. However, second-line treatment options are limited and require extensive chemotherapy (up to 2 years of treatment) with medicines that are expensive and toxic. Extensively drug-resistant TB (XDR TB) is a rare type of multidrug-resistant tuberculosis (MDR TB) that is resistant to isoniazid and rifampin, plus any fluoroquinolone and at least one of three injectable second-line drugs (i.e., amikacin, kanamycin, or capreomycin). ^{3,4}

Despite the brief decline in TB notifications observed around the months corresponding to India's two major COVID-19 waves, the National Tuberculosis Elimination Programme (NTEP) reclaimed these numbers. Accordingly, 2021 witnessed a 19% increase from the previous year in TB patients' notification—the total number of incident TB patients (new and relapse) notified during 2021 were 19,33,381 as opposed to that 16,28,161 in 2020. ⁵

The revised National Tuberculosis Control Program (RNTCP) is a program for the prevention and control of TB in India by the Ministry of Health and Family Welfare, Government of India. It has integrated four strategic pillars of "Detect – Treat – Prevent – Build" (DTPB) under the National Strategic Plan 2017-2025 for achieving the goal of TB elimination by 2025.

In 2020, after the completion of 3 years of mission to End TB (2017-2025), the program is renamed as "National Tuberculosis Elimination Program (NTEP)" from the Revised National Tuberculosis Control Program (RNTCP). The theme for 2021 is 'The Clock is Ticking'.⁷

While there is growing momentum in the development of new strategies to control the spread of TB and to reduce the incidence and prevalence rates of TB, the cornerstone of TB control remains anti-tuberculosis drugs. Irrespective of multiple efforts taken by the government, tuberculosis patients' adherence to treatment is poor. Poor treatment adherence among patients with tuberculosis (TB) lead to drug resistance, and increased risk of morbidity, mortality, and transmission of the disease in the community.

Knowledge and data are powerful weapons in the fight against tuberculosis. The WHO Global TB report delivers a clear message that dedicated, sustained acceleration of efforts, fully funded, and increased collaboration is urgently required to turn the tide of the TB epidemic. ^{8,9}

The government of India is making a lot of efforts to bring down the problems associated with TB. Despite this, there is a long way to go to achieve a significant reduction in the high incidence and prevalence of TB in India. Factors like lack of awareness and resources, poor infrastructure, increasing drug-resistant cases, poor notification, and overall negligence are the major challenges. The present study was conducted to evaluate the treatment completion rates among tuberculosis patients and factors that affected the adherence to treatment of tuberculosis

Methodology

The present observational study was conducted for a period of 6 months, between August 2022 and February 2023 in the districts of Haryana. Ethical approval was taken for this study.

The enumerated sample size of the study is based on the assumptions:

Confidence Level = 95%

Precision (d) = $\pm 2.0\%$

Outcome Parameter = Compliance rate = 81% [1]

The formula used to calculate the sample was, n=Z2*P*(1-P)/d2, Where 'n' denotes the sample size, 'Z' denotes the Value of standard normal variate corresponding to α level of significance, 'P' denotes the likely value of the parameter and 'd' denotes the margin of errors which is a measure of precision. The minimum sample size was 200, the survey was done for these TB patients. Out of this complete data was there for 126 patients only. The questionnaire had sections: regarding socio-demographic status, family details, housing and sanitation, diagnosis and treatment of TB, adherence to medication treatment, and knowledge, of TB. It was pilot tested on 30 TB patients who were not part of this survey. The Cronbach's alpha coefficient in the present research, was 0.788 indicating acceptable internal consistency

Participants giving informed verbal consent aged >13 years, with smear +ve pulmonary tuberculosis or smear –ve but CXR suggestive of pulmonary tuberculosis. Patients with suggestive results in CBNAAT of pulmonary tuberculosis were included. Participants <13 years of age, suffering from other diseases except pulmonary tuberculosis and not giving informed verbal consent were excluded. Informed Verbal Consent was obtained in the study before collecting data. The examination of records of TB patients in PHCs was done in the districts of Haryana and studying the extent of compliance of TB treatment by the patients from records. All screening evaluations were completed and reviewed to confirm that patients meet all eligibility criteria before enrollment.

Statistical analysis

Data were analyzed using Statistical Package for Social Sciences (SPSS) version 21, IBM Inc. Descriptive data were reported for each variable. Summarized data was presented using Tables and Graphs. Data were not normally distributed as tested using the Shaperio-Wilk W test (p-value was less than 0.05). The chi-square test was used for categorical variables. multinominal Logistic Regression Exploring Medication Adherence Among TB Patients. A level of p<0.05 was considered statistically significant.

Results:

The response rate for the study was 63%. The majority of the patients were male (67.5%), in the age group of 41-60 years (37.3%), married (81%), and had no formal education (42.9%). Financial status was further studied based on occupation, monthly income, type of housing, and number of rooms. (Table 1)

Considering the living conditions of tuberculosis patients, a total of 77.8% were found to have a separate room as a kitchen whereas 54% utilize wood, crop residue, or Dung cake as cooking fuel. Among the patients, 66.7% use pipe water at home as the main source of drinking water. There is adequate natural light and air in 90.5% of the households. It was reported that 88.9% of the patients uses their flush toilets as well. No significant association of living conditions was seen with adherence level (Table 2)

The significant symptoms experienced at the onset of Tuberculosis infection with adherence level were weight loss (51.5%), fatigue (56.3%), Night sweats (49.2%), chest pain (50.8%), loss of appetite (50.8%), breathing problem (54%) and vomiting with blood (50%).

Almost 63% of patients continued their treatment for 6-9 months, resulting in recovery among 60.5%, the demise of 19% of patients, and only 6% restarted their treatment. A minimal population of 0.5% took medications from subcenters, 12.5% from primary health centers, 13% from community health centers, 39% from district hospitals, 3% from private hospitals, and 17% from ASHA.

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It was reported that 36% of Tb patients reached 10 mins from their residence to the medical facility by walking (47.5%). Most (70.5%) of the patients were satisfied with the mode of delivery for medicines, except a few (2%) who reported a doctor's absence most of the time and misguidance by healthcare staff. Only 8% of individuals forgot to take their TB pills, a few (1.5%) reported not taking their medications on some days, and 3% stopped their medication as they felt worse. Only 11% of patients forgot to take their medications while traveling, and 3.5% of individuals stopped taking medications as they felt their condition is under control. TB patients occasionally (12.5%) found difficulty remembering their medications.

Patients questioned about awareness regarding TB therapy reported side effects (46.5%) and mostly experienced tiredness (7.5%). A total of 17.5% of TB patients reported their experience to ASHA/Doctor. Among 4.8% of patients non-adherence to TB treatment was seen as 95.2% the patient were regularly taking medicine. Family supervision for taking medication was often (52%) reported. Awareness about DOTS was found to be very low (5%), 3.5% reported DOTS duration as 6 months, and 44% of individuals reported that they don't know that tuberculosis can be cured by DOTS. TB patients stated that tuberculosis can be transmitted (54.5%) by coughing without covering the mouth (35.5%), sharing cutleries, plates, cups, etc (21%), indiscriminate/ careless spitting (6.5%), overcrowding (3.5%), through the air (2%), singing (0.5%), sneezing (4%), lack of proper diet (3.5%) and others including smoking (1%) and drinking (0.5%).

Knowledge regarding the diet to comply with TB treatment was high (64%) among the patients and 49% of individuals follows the diet every time as required.

The overall adherence of TB participants to treatment suggested that the individuals who sometimes forgot to take their pills (16,12.6%), who didn't take their pills over any days in the past two weeks (3, 2.3%), and those who cut back or stopped taking their medications (6, 4.7%), those who travel or leave home without sometimes taking their medications (22, 17.4%), those who feel that their condition is under control and stop taking medications (7, 5.5%), those who consider that the drug they are taking is too much had significantly higher chances of dying.

Discussion:

Despite the temporary drop in TB notifications seen in 2020 and 2021, NTEP surpassed these figures. With a record-breaking notification of 24.2 lakh cases in 2022—up 13% from 2021—this year is significant for India's TB surveillance efforts. This amounts to a notification rate for instances of about 172 per lakh people. Additionally, at that time, 7.3 lakhs of private TB case notifications were received, which is a record. 63,801 patients with MDR/RR will have received a diagnosis in 2022. The above achievement within the program was made possible by maintaining the pace of locating overlooked TB patients by bolstering the case-finding efforts (both passive and active case-seeking). ^{5,6} In the present study information on the knowledge, awareness, practices, and adherence to treatment towards TB is offered.

Overall, only 95.2% of TB patients reported having adherence to their anti-TB drug regimen, which indicated that medication adherence among TB patients was not particularly high. Additionally, several factors were linked to medication adherence, thus it is critical to investigate the causes and develop workable solutions to increase medication adherence.

In the present study, medication adherence was found to be significantly associated with the married person which may be because these patients have greater responsibility and more life experiences, and stronger ideology that led them to adhere more strongly to their anti-TB medicine regimen.

In addition, we found that age, monthly income, gender occupation, and qualification exhibited insignificant medication adherence.

Several other factors, such as having separate rooms as a kitchen, cooking fuel, source of drinking water, adequate sunlight, and toilet use were not found to be significantly associated with medication adherence.

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The study we conducted revealed that relapse TB patients were more likely than newly diagnosed patients to demonstrate poor treatment adherence. In contrast to relapse patients, who may believe that the disease will return even if it is temporarily treated and who may also need more involved treatment, new TB patients may have greater confidence and determination to overcome the disease, which makes it easier for them to take the anti-tuberculosis medication in time and quantity.

The current survey found that 54% of respondents had a strong general knowledge of TB. In contrast to a study conducted in Iran, where 62% of participants had a good awareness of TB, the current study found that 54% of participants had a general understanding of the disease. The aforementioned results, however, were better than those of a study conducted in Thailand, where 74.2% of participants had inadequate knowledge about tuberculosis. ^{10,11}

The extent of awareness of tuberculosis in our study was comparable to that of studies conducted in other contexts. In Shinile Town, a study found that 94.9% of people had heard of TB. Another study revealed that 92.8% and 95.6% of the study participants were aware of the disease, respectively, in the middle and lower Awash valleys of the Afar area of Ethiopia. Libya and Iraq likewise revealed that, respectively, 95%, 96%, and 91% of respondents had heard of TB. The differences could be explained by the fact that participants in the current study came from rural communities, whereas those in prior studies came from towns and cities and received their information about TB from the media and health professionals. ¹²⁻¹⁵

But in the current study, the majority of them responded to the sign and symptoms of TB in a good way which was consistent with studies done in southwest Ethiopia, northeast Ethiopia, Iran, and the Philippines. ^{13,15-17}

This investigation demonstrates predictors strongly linked to infection prevention knowledge and behavior based on the thorough survey data gathered. Drivers of knowledge and behavior are often similar in magnitude for the majority of indicators. Higher socioeconomic level patients have much more knowledge of the mechanisms behind infection and are more willing to practice preventative measures, as indicated by

education, labor force involvement, or income. A significant portion of patients does not adopt behaviors that stop the spread of TB to close contacts or to contacts outside the home while having a relatively high understanding of how the disease is disseminated. This implies that patients' adoption of infection protection behaviors has a lot of space for improvement.

Although many TB patients live in overcrowded conditions without access to separate sleeping spaces, this may contribute to the low rates of patients sleeping apart to minimize disease transmission within the family. Medication adherence significantly increased in participants who had full awareness of TB prevention and therapy. Low medication adherence was independently connected with ignorance of TB, according to a case-control study conducted in Kenya. ¹⁸

Although the majority of pulmonary TB patients can be cured with consistent drug use, the current survey indicated that some participants were uncertain about whether the condition could be cured and others were unclear of the suggested period of therapy. To increase drug compliance, thorough training and counseling at the beginning of TB treatment are essential. ¹⁹⁻²¹

Our findings repeatedly show that patients can gain knowledge from their medical experiences. Greater knowledge and prevention behaviors are linked to having a personal or family history of tuberculosis, and knowledge is also much higher at the end of therapy compared to the beginning. This may be the outcome of competent counseling provided by medical personnel or DOTS provider

The results of our research offer helpful information for future study and policy. They do imply that groups with low socioeconomic levels are more likely to lack understanding about and fail to adopt preventative behaviors, which may help attempts to more effectively target counseling and follow-up activities. The findings also imply that patients do gain knowledge about the illness and how infections occur via their interactions with medical professionals or DOTS providers. We do, however, demonstrate more constrained communication effectiveness when it comes to taking appropriate

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action. To improve the quality of care, it is essential to reinforce communication about crucial information for TB patients. More study is required to determine the best ways to motivate patients to change their behavior about spreading the disease.

Conclusion

The overall result of the study depicts that there is a significant gap in knowledge and preventive practice toward TB control. It is a well-known fact that knowledge can influence people's practices regarding prevention. There is generally a need for concerned stakeholders to step-up efforts in ensuring consistent TB enlightenment, while improving access to TB care is essential, perhaps by instituting necessary support systems including financial incentives/subsidies for TB patients generally. Also, the TB primary care provider should consistently re-evaluate the possible reason(s) for TB treatment non-adherence during provider-patient encounters and endeavor to offer essential psychological support through value-added counseling, to increase treatment outcomes and success rate.

TABLE 1: Medication Adherence Level by Demographic Characteristic

Variable	Description	N (%)	LOW	MEDIU M	HIG H	CHI- SQUAR E TEST
Gender	Male	85 (67.5)	66 (66)	13 (68.4)	6 (85.7)	0.558, NS
	Female	(32.5)	34 (34)	6 (31.6)	1 (14.3)	
	Transgend er					
	< 21 years	11 (8.7)	7 (7)	3 (15.8)	1	0.702, ns

Age					(14.3	
(years))	
	21-40	27	23 (23)	3 (15.8)	1	_
	years	(21.4)			(14.3	
)	
	41-60	47	36 (36)	7 (36.8)	4	_
	years	(37.3)		(3 2 2 2 7	(57.1	
)	
	More than	41	34 (34)	6 (31.6)	1	-
	60 years	(32.5)			(14.3	
),	
Qualificati	No formal	54	45	5 (26.3)	4	0.699, ns
on	education	(42.	(4	(=335)	(57.1	
		9)	5))	
	Middle	30	24	5 (26.3)	1	_
		(23.	(2		(14.3	
		8)	4))	
	Secondary	30	23	5 (26.3)	2	
		(23.	(2		(28.6	
		8)	3))	
	Senior	7	4	3 (15.8)	0 (0)	
	Secondary	(5.6)	(4)			
	Graduate	4 (3.2)	3	1 (5.3)	0 (0)	_
			(3)			
	Postgradu	1 (0.8)	1	0 (0)	0 (0)	1
	ate		(1)			
Occupatio	Salaried	1 (0.8)	1	0	0	
n	governme					
	nt					

	Salaried	11 (8.7)	10	0	1	
	private					
	Self-	19	12	5	2	
	employed	(15.1)				
	Farmer	12 (9.5)	11	1	0	
	Artisan	13	10	3	0	
		(10.3)				
	Housewife	30	26	4	0	
		(23.8)				
	Students	7 (5.6)	4	3	0	
	Unemploy	22	19	2	1	
	ed	(17.5)				
	Labor	8 (6.3)	5	1	2	
	Retired	3 (2.4)	2	0	1	
Martial	Unmarried	20	16 (16)	3 (15.8)	1	0.020*,
status		(15.9)			(14.3	sig
)	
	Married	102	83 (83)	13 (68.4)	6	
		(81)			(85.7	
)	
	Divorced	4 (3.2)	1 (1)	3 (15.8)	0 (0)	
	or					
3.6 .11	widowed					
Monthly income (in	<10,000	98	76 (76)	16 (84.2)	6	0.966, ns
income (in		(77.8)			(85.7	
Rs))	
	10,000-	16	14 (14)	1 (5.3)	1	
	20,000	(12.7)			(14.3	

)	
21,000-	1 (0.8)	1 (1)	0 (0)	0 (0)	
30,000					
31,000-	10 (7.9)	8 (0.8)	2 (10.5)	0 (0)	
40,000					
41,000-	1 (0.8)	1 (0.8)	0 (0)	0 (0)	
50,000					
More than	0 (0)	0 (0)	0 (0)	0 (0)	
50,000					

TABLE 2: Medication Adherence Level by Social Characteristic

Variable	Description	N (%)	LOW	MEDIU M	HIGH	CHI- SQUAR E TEST
No family membe	1-5	63 (50)	49 (49)	(52.6)	4 (57.1)	0.472, ns
rs	5-10	51 (40.5)	40 (40)	9 (47.4)	2 (28.6)	
	10-15	7 (5.6)	7 (7)	0 (0)	0 (0)	
	15-20	3 (2.4)	2 (2)	0 (0)	1 (14.3)	
	20-25	2 (2.4)	2 (2)	0 (0)	0 (0)	

Is any	Yes,	20	14	5 (26.3)	1	0.657, ns
of your	Infected	(15.	(1		(14.3)	
family		9)	4)			
membe						
r	No, Not	106	86	14 (73.7)	6	_
have/h	Infected	(84.	(8		(85.7)	
ad TB?		1)	6)			
Type of	Kaccha	37	30 (30)	5 (26.3)	2	0.587, ns
House	House	(29.4)			(28.6)	
	(Juggi-					
	Jhopdi)					
	Pucca	59	45 (45)	9 (47.4)	5	
	House	(46.8)			(71.4)	
-	Semi pucca	30	25 (25)	5 (26.3)	0 (0)	
		(23.8)				
Numbe	1-3	105	82 (82)	16 (84.2)	7 (100)	0.789, ns
r of		(83.3)				
rooms	3-6	20	17 (17)	3 (15.8)	0 (0)	
		(15.9)	17 (17)	3 (13.0)	0 (0)	
<u> </u>	6-9	, ,	1 (1)	0 (0)	0 (0)	
Do you		1 (0.8)	1 (1)	0 (0)	0 (0)	
Do you	Yes	98	80	13	5	0.494, ns
have a		(77.8%	(80%)	(68.4%)	(71.4	
separat)			%)	
e room with a	No	28	20	6	2	
kitchen		(22.2%	(20%)	(31.6%)	(28.6	
?)			%)	
Type of	LPG	50 (45)	45 (45)	0 (45.4)	4	
cookin	LIU	58 (46)	45 (45)	9 (47.4)	(57.1)	
g fuel					(57.1)	
5 1001	Kerosene	0 (0)	0 (0)	0 (0)	0 (0)	-
	HOLOSOHO	0 (0)	0 (0)	0 (0)	0 (0)	

	Wood/Crop residue/Dun g Cake Charcoal/C oal	68 (54) 0 (0)	55 (55)	10 (52.6) 0 (0)	3 (42.9) 0 (0)	
What is	Pipe water	84	70 (70)	11 (57.9)	3	0.100, ns
the	at home	(66.7)			(42.9)	
main	Public	23	15 (15)	6 (31.6)	2	
source	Tap/Stand	(18.3)			(28.6)	
of	Tap					
drinkin						
g	Well/ Hand	11 (8.7)	10 (10)	1 (5.3)	0 (0)	
water?	pump/ Bore					
	well					
	Bottle/	8 (6.3)	5 (5)	1 (5.3)	2	
	Tanker/				(28.6)	
	Truck					
Is there	Yes	114	90 (90)	17 (89.5)	7 (100)	0.675, ns
adequa		(90.5)				
te	No	12 (9.5)	10 (10)	2 (10.5)	0 (0)	
natural		(>)		_ (=355)		
light						
and air						
in the						
house?						

Which toilet do you	Use your own flush toilet	112 (88.9)	90 (90)	15 (78.9)	7	0.062, ns
use?	Community Toilet	9 (7.1)	8 (8)	1 (5.3)	0	
	Open defecation	5 (4)	2 (2)	3 (15.8)	0	

Table 3 Medication Adherence Level by TB Patients' Symptoms

Variable	Description	N	LOW	MEDIUM	HIGH	Chi-
		(%)				square
						test
Symptoms	Yes	119	95	17 (89.5)	7	0.505,ns
experienced		(95.5)	(95)		(100)	
at the onset	No	7 (55.5)	5 (5)	2 (10.5)	0 (0)	1
of TB						
infection:						
cough						
Weightloss	Yes	65	44	15 (78.9)	6	0.004*,
		(51.5)	(44)		(85.7)	sig
	No	61	56	4 (21.1)	1	1
		(48.4)	(56)		(14.3)	
Fatigue	Yes	71	50(50)	15 (78.9)	6	0.018*,
		(56.3%)			(85.7)	sig
	No	55	50(50)	4 (21.1)	1	1
		(43.7%)			(14.3)	
Fever	Yes	86	64	16 (84.2)	6	0.132,
		(68.3)	(64)		(85.7)	ns

	No	40	36	3 (15.8)	1	
		(31.7)	(36)		(14.3)	
Night sweat	Yes	62	42	14 (73.7)	6	0.006*,
		(49.2)	(42)		(85.7)	sig
	No	64	58	5 (26.3)	1	
		(50.8)	(58)		(14.3)	
Chest pain	Yes	64	44	14 (73.7)	6	0.010*,
		(50.8)	(44)		(85.7)	sig
	No	62	56	5 (26.3)	1	-
		(49.2)	(56)		(14.3)	
Appetite	Yes	64	44	14 (73.7)	6	0.010*,
		(50.8)	(44)		(85.7)	sig
	No	62	56	5 (26.3)	1	
		(49.2)	(56)		(14.3)	
Breathings	Yes	68 (54)	47	14 (73.7)	7	0.004*,
			(47)		(100)	sig
	No	58 (46)	53	5 (26.3)	0 (0)	
			(53)			
Vomiting	Yes	63 (50)	43	14 (73.7)	6	0.007*,
			(43)		(85.7)	sig
	No	63 (50)	57	5 (26.3)	1	
			(57)		(14.3)	
Duration of	Less than 6	34 (27)	24 (24	5 (26.3)	5	0.168,
treatment	months)		(71.4	ns
)	
	6-9 months	80	67 (11 (57.9)	2 (
		(63.5)	67)		28.6)	
	9-12 months	11 (8.7)	8 (8)	3 (15.8)	0(0)	
	More than 12	1 (0.8)	1 (1)	0(0	0(0)	
	months)		
Overall	The patient is	8 (6.3)	5 (5)	1 (5.3)	2	0.001*,
assessment	on medication				(28.6)	Sig

Treatment	13	8 (8)	5 (26.3)	0 (0)
Completed	(10.3)			
Cured	92 (73)	81	10 (52.6)	1
		(81)		(14.3)
Defaulted/	3 (2.4)	2 (2)	1 (5.3)	0 (0)
discontinued				
Failed	5 (4)	2 (2)	2 (10.5)	1
Treatment				(14.3)
Died due to	5 (4)	2 (2)	0 (0)	3
TB or other				(42.9)
causes				

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