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**An epidemiological assessment of health status among a cohort of tuberculosis survivors:
prospective research in a western Indian city**

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Abstract

Long-term follow-up of tuberculosis (TB) is important to monitor treatment outcomes, prevent relapse, and improve patient care. The aims of the current study are: i) to assess various epidemiological parameters among TB survivors, like mortality and morbidity, with emphasis on recurrence status during pre-defined long-term follow-up; ii) to assess factors responsible for the recurrence of TB among study participants. A prospective observational study was conducted among cured cases of pulmonary TB registered at the TB unit of Ahmedabad City, India. As per the calculated sample size, 180 study participants were recruited by systematic random sampling from a list of cured TB cases from July to September 2021. Follow-ups of participants were conducted at 6, 12, 18, and 24 months post-recruitment. The status of cured cases was assessed by a pre-validated questionnaire. Factors significantly associated with the likelihood of TB were analyzed using logistic regression. Of the total 180 cured TB cases, 22 (12.2%) developed recurrent TB, and 12 (6.6%) deaths were recorded during the entire follow-up duration of 2 years. Among the cases assessed, 106 (71.6%) were found to be asymptomatic in the context of TB at 2 years post-treatment completion. Around 17 (77.2%) recurrent cases were diagnosed within a year of treatment completion. Factors significantly associated with recurrence were age ($p=0.01$), body mass index ($p=0.02$), and socio-economic status ($p=0.03$) of the study population. Overall recurrence assessed during 2 years of post-treatment follow-up among the cohort of TB survivors was 12.2%. As per the study findings, socio-demographic and nutritional factors play a significant role in the development of recurrent TB, highlighting the importance of targeted interventions.

Key words: tuberculosis, post treatment follow-up, recurrence.

Introduction

Tuberculosis (TB) remains a global health concern, affecting millions of individuals annually and posing significant challenges to public health systems. As per WHO, around 1.3 million people died from TB in 2022 globally [1]. Tuberculosis turns to be the second leading infectious killer after COVID-19 (above HIV and AIDS). Around 3,42,000 TB related deaths were reported in India during the year 2022. India accounted for the highest number of TB cases in the world in 2022, with 2.8 million TB cases, representing 27% of the global burden.

Looking at the current trend pertaining to Tuberculosis, multi-pronged strategies would be required to achieve the global target to End TB by 2035. While considerable progress has been made in the diagnosis and treatment of TB, the long-term health outcomes of those who successfully completed their treatment regimens also need attention. The recurrence of tuberculosis remains a significant indicator of the effectiveness of TB treatment, and it profoundly affects patients [2]. Countries with high TB incidence often experience elevated recurrence rates [3]. A systematic review reported 10% recurrence after successful treatment among patients treated under DOTS regimen in India [4]. A study conducted in the state of Gujarat during the year 2013 also reported the recurrence rate of 10.8% [5]. With reforms in strategies pertaining to programmatic management of TB, it is important to assess the current trend of recurrent TB among cured cases. Emphasize should also be given to the factors that contribute to the recurrence. Effective surveillance and follow-up of all TB patients who have completed their treatment needs to be ensured. As per the National Tuberculosis Elimination Programme (NTEP) guidelines, long term follow up of cured TB cases at 6,12,18 and 24 months is to be done by health workers [6]. Despite of its implementation, data pertaining to the status of the same is not available on extensive literature search. The current study was conducted in Ahmedabad, the largest city in the state of Gujarat and the seventh-largest urban agglomeration in India, with a population of approximately 7.4 Million [7]. Study focussed on the health status of tuberculosis survivors during the critical two-year post-treatment period. Rate of recurrence and factors associated with it was also assessed by carrying out follow up of cured TB cases at 6,12,18 and 24 months post treatment completion. The findings of this research hold the potential to inform health policies pertaining to post-treatment care protocols.

Materials and Methods

A prospective observational study was conducted among 180 cured cases of pulmonary tuberculosis at Ahmedabad city, Gujarat. The sample size was determined using the formula $4pq/l^2$, considering a recurrence rate of 10% with a 5% margin of error and a response rate of 75% [4,8]. The adjusted sample size calculated to be 174 which was rounded up to 180. Multi-stage sampling method was used in the study. Under NTEP, Tuberculosis units are established in the Ahmedabad Municipal Corporation (AMC) where all the TB cases attending government or private health care facilities of Ahmedabad City are notified. All the services related to Tuberculosis are provided by the tuberculosis units. Sampling frame comprised of TB cases registered at TB Units of AMC. At the time of study there were a total of 23 Tuberculosis units within the Ahmedabad Municipal Corporation providing TB-related care. Considering economic and time constraints 50% of TB units (i.e. 12 TUs) were selected randomly using computer-generated random numbers. A list of cured TB patients was obtained for each selected TB unit. Systematic random sampling was then applied, using an appropriate sampling interval, to select 15 cases from each TB unit. Patients not willing for participate or patient not traceable due to migration or due to any other reasons were excluded, and the next patient was enrolled in their place. Patients found to have recurrence during any follow-up visits were also excluded from further visits.

Inclusion criteria: All the patients diagnosed with Drug sensitive or drug resistant pulmonary tuberculosis who were declared cured during July- September 2021. Patients willing to provide informed consent or assent (as applicable), were included irrespective of their age.

Study method

A pretested and pre-validated questionnaire was used for data collection. Personal interviews were conducted at the time of home visits during the first and last visits (at 6 and 24 months post treatment completion), while telephonic interviews were conducted as a part of second and third follow-up (at 12 and 18 months post treatment completion). Socio-demographic and tuberculosis profile details of the participants were collected using proforma during the first home visit, whereas presence of symptoms or recurrence was assessed during all four visits.

Study definition

A previously treated TB case was defined as an individual who has been diagnosed with tuberculosis and has received treatment for the disease in the past, whether they completed the full course of treatment or not. This category includes those who have relapsed after treatment, those who were previously treated but failed to respond, and those who have returned after defaulting on their treatment regimen.

Recurrence was defined as participants identified as microbiologically confirmed pulmonary tuberculosis during survey and/or on current TB treatment among those with a reported history of TB treatment in the past [9]. A recurrence of tuberculosis is a second episode of tuberculosis occurring after a first episode had been considered cured. Recurrence may be because of relapse or reinfection with the different strain [10].

Statistical analysis

Data were entered in Microsoft Excel and analysed using JAMOVI software. Frequency and percentages were calculated for quantitative data. Chi square test was applied as test of association. Factors significantly associated with the likelihood of TB were analyzed using logistic regression.

Ethical considerations

Permission from Institutional Ethics Committee was sought prior to data collection. Written informed consent was obtained from each participant, with guardian consent sought for paediatric patients.

Results

A total of 180 cured tuberculosis cases were followed up at 6, 12, 18, and 24 months post-treatment completion. Among them, 83 (46.1%) were aged between 15 and 30 years, followed by 49 (27.2%) cases in the 30 to 45 years age group. The mean age of the patients was 33.3 ± 15.4 years. Males constituted the majority, comprising 119 (66.1%) of the total cases. Among the patients, 21 (11.7%) were illiterate, and 109 (60.5%) were employed. Fourteen (7.8%) patients changed their occupation due to tuberculosis. Additionally, 76 (42.2%) patients were below the poverty line.

Out of the total study participants, 131 (72.8%) were categorized as new cases at the time of diagnosis, while 45 (25%) were in the retreatment group. Among total cases, 97% had drug-

sensitive tuberculosis. Among 14 (8%) cases, the sputum smear was positive at the end of the intensive phase. Tuberculosis patients having co existing diabetes were 15(8.3%). In the study, 4(2.2%) patients were having HIV infection.

Out of 180 cured cases of tuberculosis, 22 (12.2%) had recurrence. Among these, 5 (22.7%) were identified with recurrence within the first 6 months, 12 (54.5%) within 6-12 months, and 4 (18.2%) within 12-18 months after being declared cured. Only one case had a recurrence after 18 months of treatment success. A total of 12 patients died during the follow-up period at different intervals. Cause of death was enquired to the relatives of deceased, of which three participants reported tuberculosis as the cause of death. For the remaining cases, no information regarding the cause of death was available with next immediate kin. Additionally, 22 (13.8%) and 38 (25.6%) patients were lost to follow-up during the third and fourth follow-ups, respectively, primarily due to changes in address or contact details (Table 1).

Among the 131 cured cases categorized as new cases, 13 (9.9%) experienced recurrence. In contrast, among the 45 previously treated patients, 8 (17.8%) had recurrence. Among the 4 cases of drug-resistant tuberculosis, 1 had recurrence, and 1 died. However, the association was not statistically significant ($p=0.176$) (Table 2).

Table 3 shows the socio demographic and selected clinical factors associated with recurrent TB. Out of 180 cases, complete data of 128 cases was available after eliminating those who died ($n=12$) during any of the follow up visits or who were lost to follow up ($n=40$). Factors significantly associated with recurrent TB were age more than 30 years ($p=0.01$), socio economic status ($p=0.03$) and BMI ($p=0.02$) of the patients.

Factors associated with the likelihood of TB were analyzed using logistic regression. Patients having BMI less than 18.5 ($p=0.007$) and those with age more than 30 years ($p=0.01$) were found to have significantly higher odds of getting recurrence. Patients belonging to lower socio economic class and those with diabetes also had higher likelihood of developing recurrence; however these findings were not significant statistically (Table 4).

Discussion

The current prospective study was conducted among 180 cured cases of pulmonary tuberculosis, with follow-up visits at 6, 12, 18, and 24 months post-treatment. The overall recurrence rate noted at the end of the two-year follow-up was 22 cases (12.2%). Among the cured TB cases, 131 patients who underwent treatment as new cases, 13 (9.9%) had

developed recurrent tuberculosis within 2 years of treatment completion. Whereas among the 45 previously treated cases, 8 (17.8%) developed recurrence. The majority of recurrences (17 cases, 9.8%) were identified within one year of completing treatment. This finding aligns with the study conducted by Anaam et al (2023) [11], who reported that almost half of the recurrent cases occurred during the first year of the follow-up period.

In the current study, 89.5% and 71.6% of cases were healthy at the one-year and two year post-treatment follow-up, respectively. At one-year follow-up, recurrence was reported in 17 cases (9.8%), and symptoms of TB were present in 11 cases (6.3%). In a study conducted by Mathur et al (2019) [12] in Hyderabad, 76.47% of cured TB cases were healthy and working without any symptoms of TB at the one-year post-treatment follow-up. In their study, symptoms of TB were present in 26 cases (13.90%), and seven cases (4.06%) were re-diagnosed with TB. Agarwal et al. (2022) [13] conducted a one to two-year post-treatment follow-up of 248 cured pulmonary TB cases. They reported that 199 cases (80.2%) were healthy and working without any symptoms of TB at the one-year post-treatment follow-up. At the two-year follow-up, TB symptoms were present in 54 cases (19.3%). In another study conducted in South India by Thomas et al. (2005) [14], 62 cases (12%) relapsed during the 18-month follow-up period, with 48 cases (77%) relapsing within the first 6 months. Joseph et al. (2015) [15] conducted a retrospective cohort study among 1,173 cured cases, mentioned that 64.1% were healthy and 29.8% reported respiratory symptoms. In a follow-up study conducted by Sharma et al. among cured pulmonary tuberculosis patients [16], it was reported that out of 191 survivors, 23 (16.2%) developed symptoms suggestive of TB.

In the present study, 3 cases (1.7%) died at one-year post-treatment follow-up, and 9 cases (5.7%) died within one to two years post treatment completion. In the study by Agarwal et al. (2022) [13], 10 cases (5.34%) died during the one-year post-treatment follow-up. Mathur et al. (2019) reported that out of 187 index cases [12], 10 (5.3%) and 15 (8.02%) cases died at one and two years post-treatment follow-up, respectively. The cause of death in all these studies, as reported by family members, was tuberculosis.

The current study identified age over 30 years as a predictor of recurrent TB. Similar findings were reported by Agarwal et al. (2022) [13], where the risk of recurrent TB was highest among older adults (36 to 55 years). In the present study, recurrent cases were not associated with gender, marital status, tobacco consumption, HIV, or diabetes. However, recurrence was significantly associated with age, socio-economic conditions and the nutritional status of

cured TB cases. Similar findings were reported in studies conducted by Mathur et al. (2019) [12], and Agarwal et al. (2022) [13].

Anaam et al. (2023) identified various factors favoring higher recurrence, such as diabetes (15.4%), non-compliance with treatment (14.3%), pre-treatment lung cavitation (8.9%), illiteracy (7.8%), and being underweight (5.1%) [11]. Additionally, Bobokhojaev et al. mentioned that the social status of all patients with relapses corresponds to the level of poverty, which should also be taken into account [17].

In present study, around 22 (13.8%) and 38(25.6%) patients were lost to follow up during third and fourth follow up, respectively. Change in address and/or contact details were the commonest reasons behind loss to follow up. Similar findings were mentioned by Verma et al. (2005) who conducted a five-year follow-up of cured TB cases and found that only 80 patients (42.8%) could be traced, while 68 patients (36.4%) had migrated, and 39 patients (20.8%) could not be traced due to changes in address [18]. Sharma et al (2019) also encountered the similar issue of loss to follow up among cured TB cases due to altered contact details [16]. This underscores the challenges in maintaining long-term follow-up in TB management and highlights the need for improved tracking mechanisms.

Limitations

Around 38 (25.6%) patients could not be followed up due to reasons like change in contact details or migration. The accurate determination of the recurrence rate was compromised because of the same. However this attrition was taken care while calculating the sample size by considering the non-response rate of 25%.

Conclusions

The overall recurrence rate of TB was 12.2% at the end of two year follow up post treatment completion among cured cases. Out of all recurrent cases, around 17 (77.2%) were diagnosed within the first year post-treatment completion. These findings emphasize the importance of close monitoring during the initial post-treatment period. Factors such as age, BMI, and social class were found to be associated with recurrence, emphasizing the importance of addressing socio-demographic determinants in TB management. The study underscores the importance of sustained efforts in TB prevention and management, including improved surveillance and tracking mechanisms, as well as targeted interventions to address

risk factors associated with recurrence. Further research can be conducted to evaluate the economic burden and quality of life among recurrent tuberculosis cases.

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Table 1. Status of cured tuberculosis cases during each follow up visit (n=180).

Status of cured TB cases during follow up visits	6 Months N=180	12 Months N=172*	18 Months N=160*	24 Months N=148*
Normal	167(92.8)	154 (89.5)	121 (75.6)	106 (71.6)
Recurrent	5(2.8)	12 (7)	4 (2.5)	1 (0.7)
Presence of symptoms suggestive of TB ⁺	5(2.8)	6 (3.5)	5 (3.1)	2(1.4)
Death	3(1.7)	0(0)	8(5.0)	1(0.7)
Loss to follow up	-	-	22 (13.8)	38 (25.6)

* Patients who lost their life and patients who developed recurrence were excluded from further follow up visits

+ Patients having fever, cough more than 14 days, weight loss or loss of appetite were considered as symptoms suggestive of suspected tuberculosis, such cases were referred to health centres for further work up related to tuberculosis.

Table 2. Association between type of tuberculosis and status of cured cases on long-term follow-up (n=180).

Type of TB case	Status of cured cases at the end of two years follow up				
	Normal	Recurrence	Death	Loss to follow up	Total
New	82(62.5%)	13(9.9%)	6 (4.6%)	30 (21.3%)	131
Previously Treated	22(48.9%)	8(17.8%)	5(11.1%)	10(22.2%)	45
Drug Resistant	2(50%)	1(25%)	1(25%)	0	4
Total	106	22	12	40	180

*Row wise percentages, Chi- square value 8.96, p value 0.176

Table 3. Association of socio-demographic and clinical variables with tuberculosis recurrence (n=128).

Variables		Status		Chi square value	p value
		Normal (n=106)	Recurrent (n=22)		
Age group(Years)	<30	65(90.3%)	7(9.7%)	6.4	0.011
	≥30	41(73.2%)	15(26.8%)		
Gender	Female	38(84.4%)	7(15.6%)	0.13	0.71
	Male	68(81.9%)	15(18.1%)		
Literacy status	Illiterate	9(69.9%)	4(30.8%)	1.8	0.171
	Literate	97(84.3%)	18(15.7%)		
Employment status	Employed	58(78.4%)	16(21.6%)	2.4	0.120
	Unemployed	48(88.9%)	6(11.1%)		
Socioeconomic condition	APL	64(88.9%)	8(11.1%)	4.2	0.03
	BPL	42(75%)	14(25%)		
Tobacco consumption	Current	26(78.8%)	7(21.2%)	2.2	0.52
	Past	11(73.3%)	4(26.7%)		
	No	67(85.9%)	11(14.1%)		
Alcohol consumption	Current	6(66.7%)	3(33.3)	3.1	0.211
	Past	7(66.7%)	2(33.3%)		
	No	96(85%)	17(15%)		
Type of TB case	New	82(86.3%)	13(13.7%)	3.2	0.196
	Multidrug Resistant	2(66.7%)	1(33.3%)		
	Previously treated	22(73.3%)	8(26.7%)		
Diabetes	Yes	6(85.7%)	1(14.3%)	0.044	0.83
	No	100(82.6%)	21(17.4%)		
HIV	Yes	3(100%)	0	0.63	0.42
	No	103(82.4%)	22(17.6%)		
Body Mass Index	<18.5	40(74.9%)	14(25.1%)	5.01	0.02
	≥18.5	66(89.2%)	8(10.2%)		

Table 4. Predictors of recurrence among cured tuberculosis cases (n=128).

Predictors*		Odds ratio	95% Confidence Interval		p-value
			Lower	Upper	
BMI	<18.5	4.41	1.55	12.9	0.007
	≥18.5	-	-	-	-
Age group	≥ 30 years	4.12	1.29	13.2	0.01
	< 30 years	-	-	-	-
Gender	Male	1.10	0.3	3.7	0.87
	Female	-	-	-	-
Diabetes Mellitus	Yes	2.40	0.24	24.1	0.45
	No	-	-	-	-
Alcohol consumption (Current or Past)	Yes	0.59	0.10	3.2	0.55
	No	-	-	-	-
Tobacco consumption (Current or Past)	Yes	0.99	0.27	3.6	0.99
	No	-	-	-	-
Below Poverty Line	Yes	2.48	0.87	7.0	0.08
	No	-	-	-	-

* Binary Logistic Regression