

Treatment success rates among drug susceptible tuberculosis patients notified from the private sector in West Bengal, India

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Abstract

In India, an estimated 50% of tuberculosis (TB) patients are diagnosed and managed by private providers (PPs). However, there is limited information on treatment outcomes among those treated by PPs largely because of a lack of systems for patient follow-up and documentation of the outcomes. Tuberculosis Health Action Learning Initiative (THALI) project implemented in six districts of West Bengal, supported PPs in managing TB patients and systematically documented the TB treatment outcomes of such patients. This provided us an opportunity to describe the treatment outcomes and assess factors associated with 'unsuccessful outcomes' among TB patients notified by PPs from January to April 2018. This was a retrospective cohort study using routinely collected data. During the study reference period, 2347 patients were notified from 389 PPs. The patient's mean (SD) age was 39.9 (17.2) years and 61% were males. Of the total, about 86% had pulmonary TB, 95% were new cases, and 23% were microbiologically confirmed (either on sputum smear microscopy or Xpert assay). Among 2347 patients, 19% received free drugs from the National Tuberculosis Program (NTP) under the supervision of PPs while the rest purchased anti-TB drugs from the private pharmacies. The 'successful outcomes' (cured and treatment completed) were seen in 86.1% (95% confidence interval (CI), 84.6%-87.4%) patients and 8.6% were 'not evaluated'. The patients who received free NTP drugs (adjusted relative risk-4.0 (95% CI: 3.1-5.0)) had a higher risk of 'unsuccessful outcomes' than those who availed of drugs from private pharmacies. The high 'successful outcomes' among TB patients treated by PPs are promising. However, higher 'unsuccessful outcomes' among patients on free NTP drugs need to be explored, and suitable corrective actions have to be taken.



Introduction

With an estimated 2.7 million new tuberculosis (TB) patients in the year 2018, India contributed to more than 25% of the estimated incident cases globally [1]. The National Tuberculosis Programme (NTP) of India has made steady progress in providing quality-assured TB diagnostic and treatment services in the public sector [2]. Despite this, an estimated 50% of the TB patients present initially to private providers (PPs) and eventually managed within the private sector [3,4].

The previous studies have reported that TB patients in the private sector are exposed to suboptimal diagnostic and treatment regimens [5,6]. Due to deficiencies in treatment adherence monitoring and patient follow-up mechanism, the TB treatment outcomes of patients managed in the private sector are rarely ascertained and reported to NTP [7,8]. Thus, there is limited information on the TB treatment outcomes of patients managed in the private sector. Even the research studies on TB treatment outcomes in the private sector are mostly limited to single tertiary care hospitals and have reported a low rate of 'successful outcomes' (cured and treatment completed) [9-11].

'Tuberculosis Health Action Learning Initiative' (THALI)' project was implemented in six urban districts of West Bengal by the consortium of non-governmental organisations (NGOs). The THALI project supported formal PPs (medical doctors with minimum qualification of Bachelor of Medicine, Bachelor of Surgery; MBBS) for providing optimal TB care at their clinics or hospitals. All formal PPs in the project districts were mapped and the project staff engaged the PPs willing to be part of the project. The field officers (FOs) of the project assisted enrolled PPs in notifying the diagnosed TB patients to NTP, provided adherence support to TB patients by making house visits and a weekly call through the 'callcentre' and tracked the patients till treatment outcome is ascertained. The project also supported PPs in procuring free NTP anti-TB drugs for managing patients who could not afford the anti-TB drugs in private pharmacies. The THALI project used a web-based information communication technology (ICT) system to report and record details of TB treatment service delivery and patient's treatment outcomes. The project incentivized PPs with 500 Indian rupees (INR) per treated TB patient for ascertaining the TB treatment outcomes and the FOs verified the reported treatment outcomes. Thus, the systematically documented treatment outcomes of a large cohort of TB patients supported under the project provided an opportunity to fill information gap on the private sector's treatment outcomes. Hence, we aimed to describe the treatment outcomes and assess the factors associated with 'unsuccessful outcomes' among drug-sensitive TB patients notified and initiated on treatment by the PPs in the six selected districts of West Bengal from January to April 2018.

Methods

Study design

This was a retrospective cohort study using secondary data collected routinely by the THALI project for programme monitoring and reporting to the NTP.

Study setting

General setting

The West Bengal state is situated in the Eastern part of India, between the Himalayas and the Bay of Bengal. During the 2011

census, the state had about 91 million population with a density of 1030 individuals per square kilometre. In 2017, around 104 thousand incident TB patients were notified to NTP in West Bengal, of which around 15% were from the private sector.

Specific setting

THALI is a USAID-funded project implemented by a consortium of three NGOs in Kolkata, Howrah, Hoogly, North-24-Parganas, South-24-Parganas, and East Medinipur districts of West Bengal.

Engagement of PPs

In 2017, all the standalone clinics, hospitals, and nursing homes with the formal PPs qualified with Bachelor in Medicine and Bachelor in Surgery (MBBS) or above in project districts were mapped. Of the total 1404 formal PPs mapped, 1050 (75%) signed a memorandum of understanding (MoU) and enrolled in the THALI project. The project had twenty-three FOs, who engaged with pre-assigned PPs. The PPs were trained on NTP guidelines for diagnosing, managing and ascertaining of treatment outcomes of TB patients. A 'call-centre' was developed to provide ICT support. The PPs could reach out to this call-centre from their registered mobile numbers during working hours to support notification, diagnosis, and treatment of TB patients.

Diagnosis, notification and treatment by THALI supported PPs

The PPs contacted the 'call-centre' and reported details of the presumptive TB patient (PTBP) detected in the health facility. The 'call-centre' alerted the respective FOs to facilitate provider and PTBP to complete the diagnostic algorithm in line with NTP guidelines. The Xpert MTB/Rif assay at a public health facility was made available free of cost for the diagnosis of all the PTBPs detected by PPs. The PTBPs with *Mycobacterium tuberculosis* bacilli detected either phenotypically (sputum smear microscopy or culture) or genotypically (Xpert assay) are considered 'microbiologically confirmed TB'. Those individuals with high suspicion of TB among PPs either based on clinical examination or through non-TB specific diagnostic tools like chest x-ray are diagnosed as 'clinically diagnosed TB'. The TB patients were classified as per NTP guidelines and the PPs informed the patient details to THALI call-centre.

The FOs supported the notification of the TB patient to the NTP. FOs contacted the patient at either the health facility or the patient's residence. The patient was registered in the 'THALI patient database' maintained at the call-centre and patient details were periodically updated. The patient was informed regarding the adherence support provided through the THALI project.

In consultation with treating PPs, the TB patients who were unable to purchase anti-TB drugs in private pharmacies were offered free drugs provided by NTP. The patient continued consulting the PP but received free anti-drugs provided by the NTP. The FOs procured NTP anti-drugs and made it available for the patient. The patients could contact the call-centre to get information related to TB and treatment. The patient used to get an adherence support call from the 'call-centre" once a week. The FO made at least three patient house visits during treatment; soon after notification, end of the intensive phase (IP) and the continuation phase (CP). In case the patient was not taking the treatment or not visited the PP as prescribed, additional visits were made to track the patients. The house visits were made only when the patient was residing in the THALI project districts. During the final house visit, FOs verified the patient's treatment card and collected details on completion of treatment and end of follow-up test results. After the patient's

house's final visit, the FOs visited the PP, verified the TB register, and discussed the doctor's treatment outcome. After physical verification of the data and discussion, the doctor made the final call to the call-centre to declare the treatment outcome. The call-centre contacted the patients on the declaration of treatment outcome and interviewed them to validate the declared treatment outcomes (Supplementary Figure 1). The programmatic TB treatment outcomes were ascertained as per the NTP guidelines of India (Supplementary Table1). The PPs were incentivised for adhering to project requirements while managing the TB patients. The PPs were offered 500 INR against three agreed deliverables while managing each patient. The first deliverable was to identify and notify the TB patient yo NTP. The second was to record the patient's status at the end of intensive phase of TB treatment. The third was to report the TB treatment outcome of the patient.

Recording and reporting

The socio-demographic and clinical details of the notified TB patients were recorded by the health assistant or the PPs in the paper-based patient registers maintained at each of the private health facilities either. The FOs supported the health assistants or the PPs in maintaining the patient registers and checked for any missing information or inconsistency in recording. The FOs informed the patient details recorded in the patient register, which were digitised at the THALI project's call-centre. The FOs documented the treatment and follow-up details in the mobile application during their patient home visit. The information captured in the mobile application was used to update the patient register maintained at the health facilities and the electronic database managed at the call-centre. The PPs recorded TB treatment outcomes in the patient register and the FOs documented the treatment outcomes in the mobile application after validation through house visit. The data in the mobile application was shared with the callcentre to update the database.

Study population

All the TB patients notified from January to April 2018 by PPs engaged with the THALI project in six urban districts of West Bengal were included in the study. The drug-resistant TB (23 during the study period) patients were excluded from the study as PPs referred these patients to public health facilities for further management and also, the THALI project did not conduct follow-up of these patients.

Data variables, sources of data, and data collection

Data on socio-demographic, clinical, and treatment characteristics like THALI case ID, age, gender, district of patient, state of patient, district of provider, type of TB (microbiologically confirmed or clinically diagnosed), site (pulmonary or extra-pulmonary), previous history of TB treatment, human immunodeficiency virus (HIV) status, diabetes mellitus status, type of health facility, education of provider, source of ant-TB drugs, programmatic TB treatment outcomes and date of TB treatment outcomes were extracted from electronic THALI patient database.

Data entry and analysis

Data extracted from the electronic database in Microsoft Excel was analyzed using Stata version 12.0 (StataCorp LP, College Station, TX, USA). Demographic, clinical, and treatment characteristics were summarized as percentages. TB treatment outcomes were summarized as the proportion with a 95% confidence interval (CI). TB treatment outcomes were categorized into successful (cured and



treatment completed) and unsuccessful (failure, lost to follow up, died, switched to category IV, and not evaluated) outcomes.

The association between socio-demographic and baseline clinical characteristics with 'unsuccessful' treatment outcomes was assessed using bivariate log-binomial regression. To assess the independent association, a cluster (individual PP) adjusted generalized linear model (Poisson regression) with variables having pvalue <0.25 in the bivariate log-binomial regression was developed. Adjusted relative risk (aRR) with a 95% CI was calculated as a measure of association.

Result

In total, 2347 TB patients were notified by 389 PPs during the study reference period. Of the notified, the mean (SD) age was 39.9 (17.2) years, and 1436 (61.2%) were males. Of the total, about 2028 (86%) of the patients had pulmonary TB, 2225 (95%) were new cases, and 1820 (77%) were clinically diagnosed. HIV status was unknown for 2037 (87%) of the TB patients, and diabetes status was unknown for 1526 (65%) of study participants. Of the 2347 notified TB patients, 365 (16%) visited PPs from a different district than where the health facility is located. The demographic and clinical characteristics of the TB patients are given in Table 1.

Of the 2347 TB patients, 2020 (86.1%, 95%CI- 84.6-87.4) had 'successful outcome'. Of the total, 201 (8.6%) were 'not evaluated'. The treatment outcomes of the TB patients stratified with receipt of anti-TB drugs from NTP and private pharmacies are described in Table 2. The reasons for 'not evaluated' were not documented under the project.

The association between patient characteristics and the unsuccessful treatment outcome is shown in Table 3. The patients who received free NTP drugs (aRR-4.0 (95% CI: 3.1-5.0)) had a higher risk of 'unsuccessful outcomes' than those who availed of drugs from private pharmacies.

Discussion

This is the first study from India assessing the TB treatment outcomes among a large cohort of drug-susceptible and mainly clinically diagnosed TB patients treated within the private sector. The private sector's treatment outcomes were promising, as 86% of TB patients had 'successful outcomes'. Despite a well-established mechanism for tracking patients through FOs and ICT support, about 9% of TB patient's treatment outcomes were 'not evaluated'. Those patients who received anti-TB drugs free of cost from NTP were at higher risk of 'unsuccessful outcomes' than those who availed it from private pharmacies.

In 2016, a study from a private tertiary care hospital in Kerala, India, reported a treatment success rate of 70% and 75% among pulmonary and extrapulmonary TB patients, respectively [12]. In 2014, a tertiary hospital of Columbia reported a treatment success rate of 36%, while 37% of TB patients were not evaluated [13]. The high rate of a successful outcome in the current study might be due to the following reasons. First, most patients (99%) were treated at standalone clinics and could have the less severe disease than patients seeking care from tertiary hospitals. Second, the TB patients in the current study received patient adherence support through the THALI project, which might have improved the TB treatment outcomes. Third, the free anti-TB drugs from NTP were



made available through the THALI project, which might have reduced the patient attrition from care due to the inability to pay for drugs at private pharmacies. The THALI project's support with anti-TB drugs from NTP meant PPs need not refer the non-affordable patients to public health facilities for further management. Thus, it limited the potential attrition during such referrals. Fourth,

Table 1. Socio-demographic, clinical characteristics and provider
related characteristics of drug-susceptible TB patients registered
for treatment with the private providers in selected districts of
West Bengal between January and April-2018.

west bengai between January and April-	2010.
Characteristics '	Total, n (%)
Total	2347 (100)
Age in years	
0-14	81 (3.5)
15-24	
	420 (17.9)
25-34	495 (21.1)
35-44	431 (18.4)
45-54	393 (16.8)
55-64	285 (12.1)
≥65	242 (10.3)
Gender	
Male	1436 (61.2)
Female	911 (38.8)
Type of TB	
Microbiologically confirmed	527 (22.4)
Clinically diagnosed	1820 (77.6)
Site of TB	
Pulmonary TB	2028 (86.4)
Extra Pulmonary TB	319 (13.6)
•	010 (10.0)
Category of TB Treatment New	2225 (94.8)
Previously treated	113 (4.8)
TA-LTFU	2 (0.1)
TAF	7 (0.3)
HIV status	
Positive	4 (0.2)
Negative	306 (13.0)
Unknown	2037 (86.8)
Diabetes status	
Diabetic	212 (9.0)
Non-diabetic	609 (26.0)
Unknown	
	1526 (65.0)
Type of health facility Clinic	2214 (08 6)
	2314 (98.6)
Hospital/Nursing home	33 (1.4)
Education of Provider	000 (97 ()
MBBS	883 (37.6)
MBBS with Diploma/MD	1464 (62.4)
District	
Kolkota	1090 (46.4)
Howrah	434 (18.5)
Hooghly	216 (9.2)
North 24 Parganas	337 (14.4)
South 24 Parganas	181 (7.7)
East Medinipur	89 (3.8)
TB care in the district of residence	
Same district	1982 (84.4)
Different district	365 (15.6)
Anti-TB drugs from	
NTP	444 (18.9)
Private pharmacies	1903 (81.1)
i mate pharmacies	1000 (01.1)

TB, tuberculosis; NTP, National Tuberculosis Programme; TA-LTFU, treatment after loss to follow-up; TAF, treatment after failure; HIV, human immunodeficiency virus; MBBS, Bachelor of Medicine and Bachelor of Surgery; MD,Doctor of Medicine. the treatment outcomes were 'not evaluated' in less than 10% of the patients than previous studies, which had 20% to 30% [14]. These 'not evaluated' were considered as 'unsuccessful outcomes'. Though the proportion with 'not evaluated' was lower in the current study compared to previous studies in the private sector, it was higher than that in the public sector (2%) in West Bengal [15].

The percentage with 'successful outcomes' among the TB patients in the private sector was on par with the 85% reported for patients treated under NTP in West Bengal [15]. However, in the current study, TB patients' treatment success rate receiving free anti-TB drugs from NTP in the private sector was relatively low (63%). The free NTP drugs were made available to only those who could not afford to purchase the drugs from private pharmacies. The majority of such patients could be from a lower socioeconomic status. We strongly believe that the lower socioeconomic status and its associated challenges than anti-TB drugs from NTP are responsible for low 'successful outcomes' in those receiving free drugs. However, few PPs reported increased adverse drug reactions among patients on fixed-dose combinations (FDC) drugs of NTP and expressed concerns on treatment adherence. There is a need for further research on the potential reason for the low 'successful outcomes' among those on anti-TB drugs from NTP.

The study has a few strengths. First, the study was conducted on a large sample of TB patients treated from about four hundred PPs, which was about 75% of all PPs in the study districts. This could have enhanced the results' external validity due to variations in patient characteristics and the variation in the TB management protocols adopted by each PP. Second, the standard protocol for ascertaining and validating treatment outcomes limited the potential biases like social desirability bias by relying only on outcomes reported by PPs and the inter-observer bias with multiple FOs involved in ascertaining the 'treatment outcomes'. Third, the data quality was assured as the project's robust data management system with internal checks was used for data capture. Fourth, the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines was used to report the study findings.

The study has certain limitations. First, the study was conducted in the THALI project districts and might not completely mimic the management of TB patients by PPs elsewhere. The patient adherence support during the treatment and the incentives to PPs for declaring the 'treatment outcomes' might have led to higher rates of 'successful outcomes' and a lower proportion of 'not evaluated'. Second, about 9% of treatment outcomes were 'not evaluated' and considered 'unsuccessful' outcomes. However, like most of the 'not evaluated' cases are unaccounted loss to follow-up (LTFU), this might not have grossly underestimated the rate of 'successful outcomes'. Third, the details of various drug regimens prescribed by the PPs were not available in the database. This limited the opportunity to study the pattern of treatment regimens used and the difference in treatment outcomes across the regimens used by the PPs. Fourth, the potential confounders like socioeconomic status, education, adherence during treatment and family support during treatment were not accounted for in the model. This could have reduced the model's validity for assessing factors associated with 'unsuccessful outcomes'. Fifth, the drug-resistant TB patients were not included in the study and their treatment outcomes have not been captured.

The study has a few implications and recommendations. First, there was a high rate of 'successful outcomes' among TB patients managed in the private sector supported by the THALI project. The NTP can adopt models similar to the THALI project to support the management of TB patients in the private sector through dedicated health workers like FOs to engage with PPs for quality TB service provision and track TB patients with adherence support.



Table 2. TB treatment outcomes of drug-susceptible TB patients registered for treatment with a private provider (stratified by source of
anti-TB drugs) in selected districts of West Bengal between January and April-2018.

TB treatment outcome	anti-TB drugs	anti-TB drugs	Total, n (%)*
	from private pharmacies, n (%)	from NTP, n (%)	
Successful Cured Treatment completed	$\begin{array}{c} 1732 \ (91.0) \\ 6 \ (0.3) \\ 1726 \ (90.7) \end{array}$	288 (64.9) 22 (5.0) 266 (59.9)	2020 (86.1) 28 (1.2) 1992 (84.9)
Unsuccessful Failure Lost to follow up Died Shift to Cat IV Not evaluated	$171 (9.0) \\ 0 (0.0) \\ 34 (1.8) \\ 10 (0.5) \\ 12 (0.6) \\ 115 (6.0)$	$156 (35.1) \\1 (0.23) \\54 (12.2) \\10 (2.3) \\5 (1.1) \\86 (19.4)$	$\begin{array}{c} 327 \ (13.9) \\ 1 \ (0.04) \\ 88 \ (3.8) \\ 20 \ (0.9) \\ 17 \ (0.7) \\ 201 \ (8.6) \end{array}$

*Percentage calculated with the total number of individuals in each group as the denominator; TB, tuberculosis; NTP, National Tuberculosis Program; Cat IV, drug regimen used to treat multi-drug resistant TB patients.

Table 3. Association of socio-demographic, clinical and provider-related factors with unsuccessful outcomes among drug-susceptible TB
patients registered for treatment with private providers in selected districts of West Bengal from January to April-2018.
patients registered for treatment with private providers in selected districts of west bengar from January to April-2010.

Characteristic	Total	Unsuccessful	Unadjusted RR	Adjusted RR	
		outcome, n (%)*	(95% CI)	(95% CI)#	p-value
lotal	2347	327 (13.9)			
Age in years				1	
0-14	81	13 (16.1)	1.5 (0.9-2.7)	1.7 (1.0-2.7)	0.038
15-24	420	44 (10.5)	1	1	
25-34	495	64 (12.9)	1.2 (0.9-1.8)	1.6 (1.1-2.1)	0.008
35-44	431	77 (17.8)	1.7 (1.2-2.4)	2.2 (1.5-3.2)	< 0.001
45-54	393	57 (14.5)	1.4 (1.0-2.0)	1.7 (1.2-2.5)	0.009
55-64	285	33 (11.6)	1.1 (0.7-1.7)	1.4 (0.9-2.2)	0.129
≥65	242	39 (16.1)	1.5 (1.0-2.3)	2.1 (1.3-3.2)	0.002
ender					
Male	1436	203 (14.1)	1.0 (0.8-1.3)		
Female	911	124 (13.6)	1		
ype of TB					
Microbiologically confirmed	527	89 (16.9)	1.3 (1.0-1.6)	1.2 (0.9-8.5)	0.164
Clinically diagnosed	1820	238 (13.1)	1	1	
ite of TB					
Pulmonary TB	2028	280 (13.8)	1		
Extra pulmonary TB	319	47 (14.7)	1.1 (0.8-1.4)		
ategory of TB		\sim			
New	2225	303 (13.6)	1	1	
Previously treated	122	24 (19.7)	1.4 (1.0-2.1)	1.1 (0.8-1.6)	0.606
IV status					
Positive	4	1 (25.0)	1.8 (0.3-9.8)		
No/unknown	2343	326 (13.9)	1		
iabetes status					
Diabetic	212	32 (15.1)	1.1 (0.8-1.5)		
No/unknown	2135	295 (13.8)	1		
ype of health facility					
Clinic	2314	320 (13.8)	1		
Hospital/Nursing home	33	7 (21.2)	1.5 (08-3.0)		
ducation of Provider					
MBBS	883	125 (14.2)	1.0 (0.8-1.3)		
MBBS with Diploma/MD	1464	202 (13.8)	1		
istrict					
Kolkota	1090	175 (16.1)	4.8 (1.6-14.6)	2.8 (0.9-8.5)	0.068
Howrah	434	54 (12.4)	3.7 (1.2-11.5)	2.5 (0.8-8.3)	0.132
Hooghly	216	22 (10.2)	3.0 (0.9-9.8)	2.0 (0.6-6.6)	0.245
North 24 Parganas	337	39 (11.6)	3.4 (1.1-10.8)	2.3 (0.7-7.5)	0.160
South 24 Parganas	181	34 (18.8)	4.6 (1.8-17.6)	3.3 (1.1-10.3)	0.041
East Medinipur	89	3 (3.4)	1	1	
3 care in the district of residence					
Same district	1982	279 (14.1)	1		
Different district	365	48 (13.2)	1.1 (0.8-1.4)		
B treatment regimen					
NTP	444	156 (35.1)	3.6 (3.0-4.3)	4.0 (3.1-5.0)	< 0.001
Private pharmacy	1903	171 (9.0)	1	1	

*Row percentage; ^tmodel adjusted for clustering at private healthcare providers; TB, tuberculosis; RR, relative risk; C, confidence interval; TA-LTFU, treatment after loss to follow-up; TAF, treatment after failure; HIV, human immunodeficiency virus; MBBS, Bachelor of Medicine and Bachelor of Surgery; MD, Doctor of Medicine; NTP, National Tuberculosis Program.



The NTP can orient the existing field staff or consider a publicprivate mix (PPM) approach to deliver support during treatment for TB patients treated under the private sector. Second, the ICT support through the 'call-centre' and incentives to PPs for ascertainment of TB treatment outcomes might have reduced the rate of 'not evaluated'. The program can try to establish a 'call-centre' with a toll-free number to assist PPs and the TB patients. Third, in the private sector, the majority of TB patients are clinically diagnosed and more than half treated without evaluation for HIV and diabetes mellitus. There is a need to train, support and audit PPs on adherence to standard TB care in India (STCI). Fourth, with high rates of 'unsuccessful outcomes' among those private TB patients receiving free anti-TB drugs from NTP, there is a need to explore the reasons for such findings. Fifth, the program can also advocate for bringing the patients opting for free anti-TB drugs from NTP to the public sector's ambit with directly observed treatment and see whether such a strategy can improve the treatment outcomes.

Conclusions

The high 'successful outcomes' among TB patients treated by PPs are promising. However, higher 'unsuccessful outcomes' among patients on free NTP drugs need to be explored, and suitable corrective actions have to be taken.

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