Improving treatment adherence among tuberculosis patients through evening DOTS in Chennai, India

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ABSTRACT

Background. Fixed days and timings of service are challenges in the care of patients with tuberculosis (TB). We assessed whether provision of evening DOTS (directly observed treatment, short course) improves treatment outcomes in a city with a working population.

Methods. We enrolled new adult patients with TB from seven tuberculous units (TUs) in this prospective cohort study. Participants were offered the option of DOTS during the day (8 a.m. to 3:30 p.m.) or evening (4 p.m. to 8 p.m.) and assigned accordingly.

Results. Of 127 patients enrolled between April and July 2017, 19 (15%) opted for evening DOTS. The number varied between the seven TUs (p=0.002). On an average, antitubercular therapy (ATT) was taken at 9:41 a.m. in the routine and 5:14 p.m. in the evening DOTS centres. Patients who were employed, left residence and returned back at 9:05 a.m. and 6:40 p.m., respectively. Around 96% (104/108) opted for day-time DOTS due to closeness of the centre to their residence. Around 74% (14/19) chose evening DOTS because of time convenience. Around 15% of patients on routine DOTS (16) had unfavourable treatment outcomes. All had favourable outcomes in the evening DOTS. Men were less likely and those without alcohol disorders were more likely to have treatment success.

Conclusion. Provision of time convenient services might improve adherence and treatment outcome.

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INTRODUCTION

An estimated 2.8 million patients had tuberculosis (TB) in India in 2015, contributing to one-fourth of the global incidence.[1] It is estimated that about 40% of the Indian population is infected with TB bacillus[2] and emergence of drug-resistant tuberculosis (DRTB) is a major threat to control of TB. A meta-analysis showed an increasing trend of DRTB from 1995 to 2015, multi-drug-resistant TB (MDR-TB) was higher among previously treated in comparison to new patients.[3] Important reasons for development of DRTB are inconsistent or partial treatment by the provider or patients including treatment interruptions, defaults, etc. The default rate was around 5% for new and 11% for retreatment patients in 2015.[1] The key focus of the RNTCP (Revised National Tuberculosis Control Programme) is to prevent DRTB by providing access to quality diagnostic services and directly observed treatment, short course (DOTS) in a decentralized manner.[4] The treatment is provided closer to the patient's residence by DOTS providers to minimize the patient's expenditure on travel and loss of wages but there are still unmet challenges for treatment completion.[5] Social assessment of RNTCP conducted in 2011 showed that in addition to sociocultural, economic and health system barriers in accessing care, other challenges include fixed days of service, inconvenient and fixed timings and waiting time, etc.[6] Almost one-fifth of the patients with poor adherence mentioned their duty schedule as a reason for missing treatment in a metropolitan city in India.[7] Loss of wages/transport charges was mentioned as a challenge during DOTS by one-fourth of the patients in a study from northern India.[8] Workload[9,10] and lack of money[9] were also reasons for interruption of antitubercular therapy (ATT). Though 12% of patients lost more than 2 months of work during treatment, they returned early to work establishing the economic benefit in a suburban area in southern India.[11] Treatment completion could be improved by efforts to minimize treatment interruptions.[12] Interventions such as reinforced counselling by health personnel, decentralized treatment, patient choice of DOTS supporter reduce default.[13] Material incentives and enablers did not show the benefit of adherence and completion of TB treatment.[14] One of the interventions which could be studied to combat the default rates especially for the employed who are unable to attend the DOTS clinic during day time might be provision of evening DOTS.[15]

Chennai is the most populous and dense district in Tamil Nadu with a population of around 46.81 lakh (4.68 million).[16] Prevalence of smear- and culture-positive pulmonary TB was estimated to be 228 and 259 per 100 000 population in Chennai, respectively.[17]

Around 20% of the population of Tamil Nadu working in organized sectors is from Chennai district, the highest among other districts (Census 2011 and National Sample Survey 2009–10). We did a study to determine the factors for treatment completion and assess whether provision of DOTS in the evening improves treatment adherence in Chennai district in 2017–18 with the following objectives: (i) to compare the treatment outcomes among new patients of TB started on category I treatment by evening DOTS and routine DOTS in Chennai district in 2017; (ii) to determine the factors for treatment completion among new patients of TB started on category I treatment by routine DOTS and evening DOTS in Chennai district in 2017.

METHODS
The proposal was submitted to and approved by the Institutional Ethics Committee of the National Institute for Research in Tuberculosis.

Our prospective cohort consisted of adult new patients of TB diagnosed and registered for category I ATT (thrice weekly intermittent regimen) in RNTCP who had not taken more than seven doses of ATT in seven tuberculosis units (TUs) in Chennai district between April and July 2017. The operational definitions used for defining the treatment outcomes were as per RNTCP guidelines. The TUs were chosen for the study in discussion with key RNTCP personnel based on case load and default rates.

Of the seven centres finalized for provision of evening DOTS, three were 24×7 hospitals; one was a clinic with morning and evening outpatient department and three were corporation centres.

After obtaining written informed consent, the participants were enrolled in the study. We collected information using a pretested questionnaire including sociodemographic characteristics, nature of employment, duration of working hours, comorbid conditions, symptoms, factors influencing adherence such as smoking, alcoholism, drug abuse, etc. The study participants were explained in detail about the routine programme schedule and taking DOTS in the centre. The participants were offered the option of taking DOTS in the day as practised in the programme (8:00 a.m. to 3:30 p.m.) or in the evening DOTS centres (between 4 and 8 p.m.). Those who opted for taking ATT in the day took it from the DOTS centre nearest to their residence as per the programme. For those who opted for evening DOTS, it was provided by identified treatment supporters in the centres between 4 and 8 p.m.. A data abstraction form was used to collect information regarding patient's treatment details, DOTS, sputum smear results at baseline, end of intensive phase (IP) and continuation phase (CP) and treatment outcome from the RNTCP treatment card. Duplicate of RNTCP treatment cards were maintained by treatment supporters for patients who took ATT in evening DOTS centres and the original treatment card was updated on a routine basis. The retrieval measures for patients who interrupted therapy were as per the RNTCP procedures. Data were entered using EpiData version 3.1 and analysed in SPSS package version 20.0.

RESULTS
A total of 127 participants started on category I ATT in RNTCP were recruited between April and July 2017. The mean age of the study participants was 40 years. Around 70% of the study participants were men and one-fifth of the study population were graduates (Table I). Almost 51% (65/127) of the study participants had ever consumed alcohol and among them 89% (58/65) were consuming alcohol in the past 6 months. Around 34% (43/127) of them had ever smoked and 88% (38/43) were smoking in the past 6 months.

Employment
Almost 59% (75) of the study participants were employed and around 50% of them worked mostly for daily wages or as temporary employees in the private sector (Table II). Around 41% (31/75) of the working population had rigid working hours. Almost 53% (40) were travelling 5 km or more to work.

TABLE I. Baseline characteristics of patients with tuberculosis in seven tuberculosis units in Chennai in 2017

Demographic characteristic		DOTS n (%)		Total (%)
		Routine	Evening	
Age (in years)	≤25	18 (17)	7 (37)	25 (20)
	25–50	63 (58)	7 (37)	70 (55)
	>50	27 (25)	5 (26)	32 (25)
Gender	Men	74 (68)	15 (79)	89 (70)
	Women	32 (30)	4 (21)	36 (28)
	Transgender	2 (2)	0 (0)	2 (2)
Educational status	Illiterate	21 (19)	2 (11)	23 (18)
	Primary	25 (23)	4 (21)	29 (23)
	Middle and high school	37 (34)	7 (37)	44 (34)
	Higher secondary	6 (6)	1 (5)	7 (6)
	Graduation and above	19 (17)	5 (26)	24 (19)
Marital status	Married	77 (71)	11 (58)	88 (69)
	Unmarried	28 (26)	8 (42)	36 (28)
	Others	3 (2.8)	0	3 (3)
House type	Kutcha	5 (5)	0	5 (4)
	Semipucca	30 (28)	5 (26)	35 (28)
	Pucca	73 (67)	14 (74)	87 (68)
Own house	Yes	35 (32)	6 (32)	41 (32)
Total		108 (85)	19 (15)	127 (100)

DOTS directly observed treatment, short course

TABLE II. Employment details of patients with tuberculosis in seven tuberculosis units in Chennai in 2017

Characteristic	Routine DOTS n (%)	Evening DOTS n (%)	Total n (%)
Employment			
Unemployed	46 (43)	6 (32)	52 (41)
Daily labourer	31 (29)	5 (26)	36 (28)
Private sector (temporary)	20 (19)	5 (26)	25 (20)
Private sector (permanent)	3 (3)	1 (5)	4 (3)
Own business	6 (6)	0	6 (5)
Others	2 (2)	2 (11)	4 (3)
Only earning member			
Yes	31 (29)	8 (42)	39 (31)
No	31 (29)	5 (26)	36 (28)
Not applicable	46 (42)	6 (32)	52 (41)
Distance from house to work			
<5 km	24 (22)	3 (16)	27 (21)
5–10 km	18 (17)	5 (26)	23 (18)
>10 km	14 (13)	3 (16)	17 (14)
Varying distance	6 (6)	2 (10)	8 (6)
Not applicable	46 (42)	6 (32)	52 (41)
Permission during working hours			
Yes	52 (48)	7 (37)	59 (47)
No	12 (11)	3 (16)	15 (12)
Not applicable	44 (41)	9 (48)	53 (42)
Flexible working hours			
Yes	37 (34)	7 (37)	44 (35)
No	25 (23)	6 (32)	31 (24)
Not applicable	46 (43)	6 (32)	52 (41)
Total	108 (85)	19 (15)	127 (100)

Distance to the DOTS centres

For 96% (120/127) of the patients, the DOTS centre was within 3 km of their residence. Around 42% (53/127) were within walking distance from the DOTS centre. On an average, patients travelled about 13 minutes to reach the DOTS centre. The mean (SD) cost per day to go to the centre was ₹10.8 (20.5) and ₹4.8 (11.9) for routine and evening DOTS, respectively. The average time at which most of the participants took their ATT was 9:41 a.m. in the routine DOTS centres and 5:14 p.m. in the evening DOTS centres. The average time for the working population to leave their residence for work was around 9:05 a.m. and return from work was 6:40 p.m. (Table III).

TU-wise details of participant recruitment

Of the 127 participants, 85% (108) and 15% (19) of the participants opted taking routine and evening DOTS, respectively. The acceptance of evening DOTS by patients in different TUs were different. While almost every other patient opted for evening DOTS in one TU, one-third of the participants opted in another, one-fourth in another and there were no takers for evening DOTS in one TU (p<0.005).

Reasons for choosing the DOTS timing

During the baseline interview, 96% (104/108) of those who opted during regular timings chose the option because of closeness of the DOTS centre to their residence. Among the patients who opted for evening DOTS at baseline, 74% (14/19) chose because of the time convenience. Other reasons for opting for evening DOTS included decision to go to work; patient caregivers who accompanied them were working during the day and closer to their work place.

Treatment outcome

Of all the patients, 105 (83%) had a favourable outcome. All the patients in the evening DOTS had a favourable outcome (cured and treatment completed) and 80% of the patients taking routine DOTS had a favourable outcome (Table IV).

Regarding the factors influencing the treatment outcome, men were less likely to have treatment success. Those who were employed were also less likely to have treatment success; however, the association was not significant. Those without alcohol disorders were more likely to have treatment success than with it. (Table V).

DISCUSSION

Of the 127 participants, 15% opted for evening DOTS while the rest chose day-time DOTS centres. The DOTS centres were

TABLE III. Time and cost factors of patients with tuberculosis in seven tuberculosis units in Chennai in 2017

Characteristic	Mean (SD)	Range
Time to reach the DOTS centre from home in minutes	13 (7.3)	1–45
Cost per day (₹) to go to the DOTS centre	9.8 (19.6)	0–100
Time starting from home in the morning	9.05 (2.5)	4–19
Time returning from work in the evening	18.4 (2.6)	7–24
Time routine DOTS patients took ATT	9.40 (0.90)	8–11
Time evening DOTS patients took ATT	17.40 (1.30)	15–19.15

DOTS directly observed treatment, short course   ATT antitubercular therapy

TABLE IV. Treatment outcome in category I participants who opted for routine and evening DOTS

Outcome	Routine DOTS n (%)	Evening DOTS n (%)	Total n (%)
Cured+treatment completed	86 (79.6)	19 (100)	105 (82.7)
Death	3 (2.8)	0	3 (2.3)
Lost to follow up	12 (11.1)	0	12 (9.4)
Failure	1 (0.9)	0	1 (0.8)
Migrated	1 (0.9)	0	1 (0.8)
Private	2 (1.9)	0	2 (1.6)
Transferred out	3 (2.8)	0	3 (2.4)
Total	108 (100)	19 (100)	127 (100)

DOTS directly observed treatment, short course

TABLE V. Factors influencing the treatment outcome among category I patients

Factors	Number of patients ($n=127$) n (%)	Treatment success ($n=105$) n (%)	RR (95% CI)
Men*	89 (70.1)	69 (65.7)	0.82 (0.72, 0.94)
≤40 years old	65 (51.2)	56 (53.3)	1.09 (0.93, 1.28)
Literate	104 (81.9)	88 (83.8)	1.15 (0.89, 1.48)
Employed	75 (59.1)	58 (55.2)	0.86 (0.74, 1.00)
Married	88 (69.3)	72 (68.6)	0.97 (0.82, 1.14)
Non-smokers	84 (66.1)	73 (69.5)	1.17 (0.96, 1.42)
Non-alcoholic†	62 (48.8)	58 (55.2)	1.29 (1.10, 1.52)

*$p<0.05$ †$p<0.01$

within walking distance for most of the patients. The most important reason for taking DOTS during the day was vicinity of the centre to their residence and in the evening was time convenience. More than half the study population was employed as temporary workers. There was interference between the timing when people took DOTS and time they left their residence to work. A study done in Delhi showed that occupational status and loss of wages were factors for non-compliance.[18] Another study from an urban setting in Delhi mentioned convenient clinic timings as an unmet need of patients.[19] Most patients who chose to take DOTS in the evening were employed, students or were accompanied to the DOTS centre by family members who were working during the day. All those attending evening DOTS and around 91% in day-time DOTS mentioned that the timing of taking DOTS was convenient. All evening DOTS patients had favourable treatment outcome while 15% of routine DOTS patients had unfavourable outcome including death, lost to follow-up and treatment failure. The proportion of people who opted for evening DOTS varied in different TUs. This suggests that prior assessment of the need for evening TB services will have to be ascertained before introducing it in different areas.

The limitation of our study is patient's selection of the intervention. The study was done in a part of an urban city, so may not be generalizable to a rural population. The small sample size is another limitation. The recruitment for the study could not be continued after the mentioned time as there was a transition from intermittent to daily DOTS in the programme.

Many of the patients and health system factors for treatment compliance are well known. The strategies used to improve compliance with varied levels of success include monetary benefits, nutritional supplement, community DOTS provider, etc. Thrice weekly intermittent regimen has been replaced by daily ATT regimen as fixed-dose combination in the programme.

Various challenges in implementation of this regimen, its impact on treatment adherence and outcome need to be studied. This also necessitates the need to study and implement various methods to improve treatment compliance including providing TB services at a time that is convenient to the patient. The need and implementation of flexible service timings and its impact on treatment outcome need to be studied extensively. With a large burden of patients with TB in India, extension of service timing, required human resource, alteration of working pattern of currently recruited staff and monetary resources are some of the challenges. The feasibility of implementation of TB services in the evening need to considered and studied against the benefits of improved cure and treatment completion rate, improved quality of life and prevention of transmission.

The effect of urban living on TB infection is mixed as there are risk factors for TB infection as well as better access to services including medical services. The purpose of evening DOTS is to make DOTS more patient-friendly and thereby improve its outreach and improve treatment outcomes in an urban setting.[20] The cost of replicating this model under programme conditions needs to be ascertained and the corresponding gain in terms of patients 'cured' by treatment must be determined—the ultimate index of benefit.

Conclusions
Further studies need to be planned to study the effectiveness of evening TB services in a larger population group. With the programme moving from DOTS to daily treatment, the convenience of TB patients to avail these services needs to be considered. Provision of NTEP services at a time convenient to the patients especially in the evening in urban settings would improve access to TB services as well improve adherence to treatment and treatment outcomes.

Conflicts of interest. None declared

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