Original Research Article

Source of previous anti-TB treatment for re-treatment TB cases registered under Revised National Tuberculosis Control Program in Pondicherry

R. Niranjjan¹*, Swaroop Kumar Sahu², Gautam Roy², S. Arul Vijaya Vani³

¹Department of Community Medicine, Aarupadai Veedu Medical College, Pondicherry, India
²Department of Preventive and Social Medicine, Jawaharlal Institute of Post graduate Medical Education and Research, Pondicherry, India
³Department of Biochemistry, Mahatma Gandhi Medical College & Research Institute, Pondicherry, India

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*Correspondence:
Dr. R. Niranjjan,
E-mail: niranjindia@gmail.com

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ABSTRACT

Background: Re-treatment TB cases are still a big challenge to National TB control programme. The objectives of the study were among re-treatment TB cases, to study the source of previous anti-TB treatment, to find the time delays in initiating re-treatment and to find the risk factors for initiating re-treatment under Revised National Tuberculosis Control Program (RNTCP) in Pondicherry.

Methods: It was a cross sectional study. Source, date of completion or interruption of recent previous anti-TB treatment, missed doses, DM status; smoking and alcohol intake in the past TB treatment were collected using pretested structured questionnaire and available records. Data was entered in EpiData software version 3.1 and analysed using SPSS v20.

Results: Of 241 re-treatment TB patients, the proportion of relapse, TAD, failure and others were 52%, 24%, 12.4% and 11.6 respectively. About 90% [95% CI (85.6-93.2)] had received their recent previous anti-TB treatment from RNTCP sources. In multivariate analysis, Age >24 years, below secondary level of education and relapse cases have independently associated with RNTCP source of previous TB treatment. The median time interval of re-registration for relapse, TAD, failure and others were 334, 211, 140 and 53 days respectively. This difference between groups are statistically significant (p<0.0001). Almost one out of four retreatment TB patient was known diabetic. More than half of retreatment TB patients had consumed alcohol during their recent previous TB treatment.

Conclusions: The public-private partnership is better in Pondicherry as only 10% of re-treatment TB cases were previously treated from Non-RNTCP sources. There is a scope for reducing the time between declaration of failure and initiation of re-treatment TB regimen. Screening and appropriate counselling of all registered TB patients for smoking and alcohol intake may be necessary.

Keywords: Re-treatment TB, Time interval, Risk factors, Treatment after default, Relapse, Failure

INTRODUCTION

Globally, the primary aim of tuberculosis (TB) control program is to reduce the morbidity and mortality due to TB by interrupting the chain of TB transmission. Re-treatment TB cases are TB patients who have been treated for one month or more with anti-TB drugs in the past.¹ These patients are a big challenge to the TB control programs as they require a longer duration of treatment, have poor treatment outcomes and an increased risk of
death. They are also more likely to transmit drug-resistant TB in the community. In 2013, 0.7 million (11.5%) of the 6.1 million global total TB notifications were re-treatment TB cases. India is estimated to have nearly one-fourth of the global TB burden. There were 274,372 notified re-treatment TB cases in 2013 which accounts for 40% of re-treatment TB cases globally. In Pondicherry, a Union Territory of India, 221 (15%) of the 1458 total TB notifications were re-treatment TB cases in 2013.

Re-treatment TB cases emerge mostly as a result of inadequate and improper treatment of the new-TB cases. In India, TB treatment is widely available from both the public (54%) and the private sector (46%). In India (2010), 44% of the re-treatment TB patients were previously treated from private sector. Identifying the source of previous anti-TB treatment of them will help in planning and strengthening of public-private-partnership for optimal delivery of the Revised National Tuberculosis Control Program (RNTCP) services. Not many studies have attempted to determine the time interval between completion/ interruption of previous anti-TB treatment and starting of re-treatment anti-TB regimen which reflects the period of on-going community spread of the disease especially in treatment after default (TAD) and failure cases. The present study could hopefully help in identifying the time gap and problem areas which need to be attend to bring down the transmission of TB. This study also finds out the known risk factors for starting of Category-II regimen.

METHODS

Study setting and population

This was a facility based cross-sectional study conducted among re-treatment TB cases registered under RNTCP in government health facilities of Pondicherry between October 2013 and December 2015. The study was approved by Institute Ethics Committee, and RNTCP State Operational Research Committee, Pondicherry. Informed written consent was taken from all study participants.

The Union Territory of Pondicherry has a population of 9.50 lakhs with two tuberculosis units and 21 Designated Microscopy Centres (DMCs) and eight medical colleges. It has an annual total TB case notification rate of about 112 per lakh population. The re-treatment TB case notification rate was 17 per lakh. The treatment success rate was more than 85% among new smear-positive TB cases. There are 29 primary health centres (13 urban and 16 rural PHCs) and two community health centres in Pondicherry. A total of 25 out of 29 Government health centres were included in the study. Government health centres that registered less than two re-treatment TB cases in last year were excluded from the study.

Sample size and sampling technique

Assuming that the previous anti-TB treatment from Non-RNTCP source as 44%, 95% CI, and 15% relative precision, the sample size required was 217. Considering the non-response rate of 10%, the final sample size needed for the present study was 238.

Study procedure

Re-treatment TB patients were interviewed during their intensive phase of TB treatment. A pre-tested semi-structured interview schedule was used to collect baseline information like socio-demographic details, type of re-treatment TB, sources of recent previous anti-TB treatment. Date/month/year of completion or interruption of previous anti-TB treatment and initiation of current Cat-II regimen were collected. Available records of the previous episode of anti-TB treatment were reviewed. Details of known risk factors like Diabetes, HIV, irregular TB treatment, smoking and alcohol status also collected. All operational definitions, viz. re-treatment TB, relapse, treatment after default, etc. were taken as defined in the RNTCP. In the present study re-treatment TB cases were further classified by the outcome of their most recent course of treatment into four categories - Relapse, treatment after default, failure and others.

Table 1: Operational definitions.

| Retreatment case of TB | A patient who has been treated for one month or more with anti-TB drugs in the past. |
|------------------------|----------------------------------------------------------------------------------|
| Missed doses           | TB patient who failed to consume a dose within the stipulated interval of two days in intensive phase (IP) or one collection within a week in continuation phase (CP). |
| Ever smoker Ever drinker | Those who had smoke anytime in the past Those who had consumed alcohol anytime in the past |
| Current smoker Current drinker | Those who had smoked in the past one month Those who had consumed alcohol in the past one year |
| Smokers or drinkers during previous episode of TB treatment | Re-treatment TB patients who had smoked or consumed alcohol at any time during their most recent course of previous TB treatment. |
Data entry and analysis

Data were collected and entered in EpiData software version 3.1. It was analysed using EpiData analysis. Socio-demographic variables, type of re-treatment TB and source of previous anti-TB treatment were reported in percentages with 95% CI. Univariate and multivariate logistic regression analysis were done to find the association between sociodemographic variables and source of previous TB treatment. The time interval between completion/interruption of previous anti-TB treatment and starting of current Cat-II regimen were expressed in median days with interquartile range. Kruskal-Wallis test was used to compare the time interval between different groups.

RESULTS

Table 2 shows socio-demographic details of the study subjects. A majority (85%) were males. The mean age for males and females was 46.2±12.8 years and 40±8 years respectively. This difference in mean age among males and females was statistically significant (p=0.01). Almost 40% were either illiterate or had studied up to the primary level. Nearly 43% of retreatment TB patients were unemployed (excluding housewives and student). The age group of 15-24 years consisted 6.2% of the study population. Almost 85% of the patients belonged to economically productive age group (25-64 years). Patients classified as registration type “relapse” represented more than half of the re-treatment TB patients registered. Ninety percent [95% CI (85.6-93.2)] of re-treatment TB cases had taken their recent previous episode of anti-TB treatment from RNTCP sources. Age >24 years, below secondary level of education and relapse cases have independently associated with RNTCP source of previous TB treatment.

Table 3 describes the details of previous anti-TB treatment regimen of 217 retreatment TB patients who were registered under RNTCP. Nearly one fourth had already taken Cat-II regimen in their recent previous course of anti-TB treatment under RNTCP. Almost 54% were relapse cases.

Table 2: Distribution of Sources of previous anti-TB treatment by various socio-demographic details among re-treatment TB cases registered under RNTCP in Pondicherry (N=241).

| Variables          | RNTCP N (%) | Non-RNTCP N (%) | Unadjusted OR [95% CI] | P value | Adjusted OR [95% CI] | P value |
|--------------------|-------------|-----------------|-------------------------|---------|----------------------|---------|
| **Gender**         |             |                 |                         |         |                      |         |
| Female*            | 33 (91.7)   | 3 (8.3)         | 1                       | 0.7     |                      |         |
| Male               | 184 (89.8)  | 21 (10.2)       | 0.7 (0.2-2.8)           | 0.7     |                      |         |
| **Age group in years** |           |                 |                         |         |                      |         |
| Age ≤ 24*          | 9 (60)      | 6 (40)          | 1                       | 0.0001  | 6.1 (1.7-21.6)       | p<0.005 |
| Age > 24           | 208 (92)    | 18 (8)          | 7.7 (2.4-24.0)          | 0.0001  |                      |         |
| **Education**      |             |                 |                         |         |                      |         |
| Below secondary    | 92 (95.8)   | 4 (4.2)         | 3.6 (1.2-11.0)          | 0.02    | 3.5 (1.0-12.2)       | p< 0.04 |
| Secondary & above* | 125 (86.2)  | 20 (13.8)       | 1                       | 1       |                      |         |
| **Occupation**     |             |                 |                         |         |                      |         |
| Unemployed         | 114 (91.9)  | 10 (8.1)        | 1.5 (0.6-3.6)           | 0.3     | 1.4 (0.5-3.7)        | p=0.5   |
| Employed *         | 103 (88)    | 14 (12)         | 1                       | 1       |                      |         |
| **Type of TB**     |             |                 |                         |         |                      |         |
| Relapse            | 117 (93.6)  | 8 (6.4)         | 3.4 (1.2-9.0)           | 0.01    | 3.8 (1.3-10.9)       |         |
| TAD*               | 47 (81)     | 11 (19)         | 1                       | 1       |                      |         |
| Failure            | 30 (100)    | 0 (0)           | -                       | -       |                      |         |
| Others             | 23 (82.1)   | 5 (17.9)        | 1.0 (0.3-3.4)           | 0.9     | 1.7 (0.4-6.3)        | 0.2     |
| **Total**          | 217 (90.9)  | 24 (10)         | [95% CI (85.6-93.2)]    |         |                     |         |
|                    | [95% CI (6.8-14.4)] |          |                        |         |                      |         |

* Reference

Of the total 241 re-treatment TB patients, records of recent previous anti-TB treatment could be retrieved for 141 re-treatment TB patients who had their treatment from RNTCP sources (Table 4). The average time interval between completion/interruption of recent previous anti-TB treatment and starting of present TB treatment was 234 days (IQR 97-576). The median time interval between completion of their recent previous TB treatment and initiation of present re-treatment regimen for “relapse”, TAD, failure and others cases were 334 days, 211 days, 53 days and 140 days respectively. The differences in time interval between various TB types were statistically significant.

Among the 100 patients whose past records could not be retrieved, 76 got their previous TB treatment from RNTCP and 24 from non-RNTCP sources.
Table 3: Categories of anti-TB regimen for patients under RNTCP* in their previous episode of TB treatment among re-treatment TB cases registered under RNTCP* in Pondicherry (2014-15); N=217.

| Type of TB case in present Category-II regimen | Previous anti-TB treatment from RNTCP | Total |
|---------------------------------------------|-------------------------------------|-------|
|                                            | Category I N (%)  | Category II N (%)  | N (%)  |
| Relapse                                    | 95 (57.2)          | 22 (43.1)          | 117 (53.9) |
| TAD                                        | 32 (19.3)          | 15 (29.4)          | 47 (21.7)  |
| Failure                                    | 17 (10.2)          | 13 (25.5)          | 30 (13.8)  |
| Others                                     | 22 (13.3)          | 1 (2)              | 23 (10.6)  |
| Total                                      | 166 (76.5)         | 51 (23.5)          | 217 (100) |

*Revised National Tuberculosis Control Programme.

Table 4: Median time interval between interruption or completion of recent previous anti-TB treatment and initiation of present Category-II regimen (N=141).

| Type of TB in present Category-II regimen | Type of TB regimen in recent previous TB treatment | Over all |
|------------------------------------------|---------------------------------------------------|----------|
|                                           | Category I Median time interval (IQR) # | Category II Median time interval (IQR) # | Median time interval (IQR)* |
| TAD (29)                                 | 20 293 (184-508) | 9 170 (88-582) | 211 (179-508) |
| Relapse (75)                              | 53 320 (174-1021) | 22 386 (158-534) | 334 (169-847) |
| Failure (29)                              | 16 24 (3-51) | 13 54 (28-154) | 53 (27-157) |
| Others (8)                                | 7 93 (44-126) | 1 --- | 140 (93-639) |
| Total (141)                               | 96 257 (107-695) | 45 195 (83-523) | 234 (97-576) |

# Inter Quartile Range, *Kruskal-wallis test

Table 5: Prevalence of known risk factors for starting of Category-II regimen among retreatment TB patients.

| Type of TB | Missed doses in intensive phase Median (IQR) | Missed drug collection during continuation phase Median (IQR) | Diabetes N (%) | HIV N (%) |
|------------|-----------------------------------------------|-------------------------------------------------------------|----------------|-----------|
| TAD        | 11 (6-15)                                     | 18 (11-22)                                                  | 11 (19.6)      | --        |
| Relapse    | 8 (1-15)                                      | 5 (3-7)                                                      | 35 (62.5)      | 1(100)    |
| Failure    | 4 (3-23)                                      | 4 (3-7)                                                      | 7 (12.5)       | --        |
| Others     | --                                            | 4 (1-5)                                                      | 3 (5.4)        | --        |
| *Average/total | *7 (3-15)                                    | *6 (4-14)                                                   | 56 (23.2)      | 1 (0.4)   |

Table 6: Smoking and alcohol status among re-treatment TB cases registered under RNTCP in Pondicherry (N=241).

| Smoking status                     | N (%) |
|------------------------------------|-------|
| Ever smokers                       | 149 (61.8) |
| Current smokers (past one month)   | 37 (15) |
| History of smoking during previous anti-TB treatment | 75 (31) |

| Alcohol drinking status            | N (%) |
|------------------------------------|-------|
| Ever drinkers                      | 182 (75.5) |
| Current drinkers (past one year)   | 142 (59) |
| History of alcohol drinking during previous anti-TB treatment | 126 (52.2) |
Table 5 describes various risk factors for starting of Category-II regimen. Treatment after default cases had more number of missed doses (median) in both intensive and continuation phase in their recent previous episode of TB treatment. Almost 23% of re-treatment TB patients were suffering from diabetes mellitus, among them 35 (62.5%) were relapse cases. One HIV (0.4%) patient among re-treatment TB cases belonged to relapse category

Table 6 shows smoking and alcohol drinking status of re-treatment TB patients registered under RNTCP in Pondicherry. Of 241 re-treatment TB patients, 149 (61.8%) were ever smokers, 37 (15%) were current daily smokers and 75 (31%) smoked during their recent previous episodes of anti-TB treatment. Similarly among 241 re-treatment patients studied, 182 (75.5%) were ever drinkers, 142 (59%) were current drinkers and 126 (52.2%) patients drank alcohol during their recent previous episode of anti-TB treatment.

DISCUSSION

Almost 80% of all health care in India is accessed from the private sector. A study from Tamil Nadu, South India reported that 38% of chest symptomatic patients first approached private health facility for their diagnosis and treatment. Similarly, a community-based survey from 30 districts of India reported that nearly half of TB patients (46%) were treated under Non-RNTCP sources, among them, 21% were re-treatment TB cases.

In the present study, the male to female (M: F) ratio of re-treatment TB patients was approximately 6:1. Studies from other parts of India have reported that M: F ratios among re-treatment TB cases were between 2:1 to 3:1. The difference could be due to the difference in age group included in various studies from India. The registration of female re-treatment TB cases in the present study was less compared to other above studies from India. The possible reason may be they were treated by private medical colleges, NGOs and other private practitioners in Pondicherry.

Ten percent of re-treatment TB cases in the present study had availed their recent previous course of anti-TB treatment from the private sector. This is a much lower figure than that reported by Sachdeva et al (44%) and Sisodia et al (74%). It appears that there is a decreasing trend of re-treatment TB cases being treated with Non-RNTCP treatment regimen in their previous episode of anti-TB treatment in India. Better involvement of private sector, especially the private medical colleges and NGOs, under RNTCP in Pondicherry could be an explanation for the finding that there was less proportion of re-treatment TB cases who availed their recent past TB treatment from Non-RNTCP sources.

Although it appears that the public-private partnership is better in Pondicherry, there is a scope for further improvement in registering more re-treatment TB cases among females and younger males under RNTCP.

Among the total re-treatment TB cases in the present study, relapse, TAD, failure and other cases were 52%, 24%, 12.4% and 11.5% respectively. The proportion of relapse cases were comparable to two other studies from Chandigarh (2005) and West Bengal (2011) which reported 48% and 63% relapse cases. An increase in the proportion of relapse cases registration under RNTCP after its nationwide implementation in India has been clearly observed. The proportion of TAD cases was comparable to other studies done in India which reported that 25% - 27% of re-treatment TB cases were TAD cases. But a study in Rajasthan, India (2003) have reported a higher proportion of TAD cases (84.6%). This could be due to those TB cases treated under private sector were reregistered under RNTCP, which was implemented in Rajasthan just two years before the commencement of this study.

The proportion of “failure” cases in the present study (12.4%) was almost two times higher than the other studies reported from India. There was one study from West Bengal, India, which reported 22.2% as failure cases among total re-treatment TB cases. The reason for the high proportion of failure cases in Pondicherry may be due to high prevalence of alcohol usage (59%) among TB patients which is consider as important cause for non-adherence to TB treatment. The present study also shows that the proportion of re-treatment patients who were registered as “others” (11.5%) was almost three times lower compared to the other studies from India, probably, these cases are being managed in one of the many medical colleges of Pondicherry which are easily accessible to the people.

The median time between completion/interruption of recent previous anti-TB regimen and initiation of the present Cat-II regimen was 234 days (IQR 97-576). Of the 141 records available, the median interval for relapse, default, others and failure was 334 days, 211 days, 140 days and 53 days respectively. A study done in Tiruvallur district, Tamil Nadu, reported that the median time interval between declaring the treatment outcome and restart of anti-TB treatment for relapse, default and failure was 210, 234 and 19 days respectively. A study from Taiwan shows that the median time between treatment completion and relapse was 1.4 years (IQR 0.7–2.2 years), which is a much longer duration compared to the present study. The difference in the study setting and study design could lead to such a big difference.

Almost 57% of relapses had occurred within the first six months of completion of treatment, the majority (72%) of relapses occurring in the first year, and 13% of relapses occurred within 1-2 years. This is comparable to a study done in Delhi, which reported that 50% of total relapses have occurred in the first six months of completion of treatment and 68.5% of relapse occur in the first year. In contrast to this, another study done in South India
showed that 77.4% of relapse occurred within the first six months of completion of treatment, and 92% of the relapses were within the first year. In the present study, the median time for re-registration of TAD cases who had taken Category-I and Category-II regimen in previous anti-TB treatment was 293 days and 170 days respectively. This difference could be due to the poor health status of patients who interrupted Category-II regimen when compared to patients who interrupted Category-I regimen. This is in contrast to the study from Tiruvallur district, Tamil Nadu which reported the median time for re-registration for subsequent Cat-II TB regimen to be 228 and 224 days for Category-I and Category -II respectively. In the present study “failure cases” who had taken Category-I regimen in previous anti-TB treatment registered early (24 days) for Cat-II regimen as compared to those who had taken Category-II regimen in their previous anti-TB treatment (54 days). This finding was comparable to the study from Tiruvallur district, Tamil Nadu, which showed that the median time intervals from previous Cat-I and Cat-II regimen failure to starting of subsequent Cat-II regimen were 18 and 72 days respectively.

Treatment after default cases had more number of missed doses (median) in both intensive and continuation phase in their recent previous episode of TB treatment. Vijay et al reported that instances of number of missed doses were independently associated with defaults of anti-TB treatment (AOR -2.56;1.82–3.57). Another study done in Tiruvallur district, Tamil Nadu reported that higher TAD cases were associated with irregular treatment in their previous anti-TB treatment (AOR 4.3; 95%CI 2.5– 7.4).

In the present study, one out of five re-treatment TB patients were suffering from diabetes mellitus. This finding is comparable to the study done by Raghuraman et al in Puducherry, who also reported that the prevalence of known diabetes among all TB patients as 20.7%. Another study from Karnataka, which reported that 23.6% were DM patients among re-treatment TB cases which is comparable to the present study. Studies from Tamil Nadu and New Delhi reported that diabetes prevalence among Cat-II TB patients was 17.7% and 15.5% respectively, which were low when compared to the present study.

Fifteen percent of the re-treatment TB patients were current smokers which is comparable to the study from Karnataka which reported that it was 18.2%. Another study from Puducherry reported that 37% of re-treatment TB patients were current smokers, however almost 31% of re-treatment TB patients in the present study had smoked during their recent TB treatment which needs specific attention. Nearly 60% of re-treatment TB patients were drinking alcohol for past one year (current drinkers). Another study from Puducherry also reported that 51% of re-treatment TB cases were current drinkers. Two more studies from India reported that current alcohol drinkers among re-treatment TB patients were 34.2% and 46%. More than half of re-treatment TB patients in the present study had consumed alcohol during recent previous anti-TB treatment. High availability and easy accessibility of alcohol in Puducherry may be the reason for higher proportion of current drinkers in the present study.

The present study is one of the few studies which deals with sources of the previous anti-TB treatment and average time gap between previous treatment status and starting of present Cat-II regimen among re-treatment TB patients registered under RNTCP. This study was conducted in all urban and rural government health facilities of Pondicherry covering 82% of re-treatment TB cases. There are few limitations in the present study. This study only reflects the picture of re-treatment TB patients who were registered under RNTCP. This study failed to assess the gap between the completion or interruption of previous anti-TB treatment and starting of symptoms of TB and also from starting of symptoms to diagnosis of recurrent TB. The present study could not also assess whether any patient delay or health system delay between completion or interruption of previous anti-TB treatment and starting of present Cat-II regimen. Records of all patients could not be retrieved.

**CONCLUSION**

Ten percent of re-treatment TB cases registered under RNTCP had taken their recent previous anti-TB treatment from Non-RNTCP sources. Overall there was less registration of re-treatment TB cases among females and younger males (15-34 years). Higher proportion of relapse cases (94%), TAD cases (81%), others (82%) and failure cases (100%) were previously treated from RNTCP sources. The median time between completion or interruption of previous anti-TB treatment from RNTCP and starting of the present Cat-II regimen was 234 days. The average gap of re-registration was more for relapse cases, TAD, other cases and failure cases were 334 days, 211 days, 140 days, and 53 days. Prevalence of diabetes and HIV among all re-treatment TB cases included in the study was 23.5% and 0.4% respectively. Almost half of the re-treatment TB patients in the present study had consumed alcohol during their recent previous TB treatment and 31% of the re-treatment TB patients had smoked during their recent previous TB treatment.

**Recommendations**

It appears that the public-private partnership is better in Pondicherry as only 10% of re-treatment TB cases were previously treated from Non-RNTCP sources and further improvement is needed for registering more females and younger male. Further studies are needed to find the reasons for high re-treatment TB cases from RNTCP sources and to elicit the time gap between completion or cure of previous anti-TB treatment and onset of symptoms of TB. It is also important to find the pre diagnostic, diagnostic and patient related delays from onset of symptoms of TB till they are initiated on re-treatment regimen. There is scope for reducing the time gap between declaration of failure in previous TB
treatment and initiation of re-treatment TB regimen. Screening and appropriate counselling of all registered TB patients for smoking and alcohol intake may be necessary, considering that a large proportion of TB patients continued to consume alcohol and smoke during TB treatment.

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