

## Original Article

**RISK FACTORS FOR NON-ADHERENCE TO DIRECTLY OBSERVED TREATMENT (DOT) IN A RURAL TUBERCULOSIS UNIT, SOUTH INDIA**

P.G. Gopi, M. Vasantha, M. Muniyandi, V. Chandrasekaran, R. Balasubramanian and P.R. Narayanan

*(Original version received on 1.6.2006. Revised on 3.8.2006. Accepted on 9.1.2007)***Summary****Objective:** To identify risk factors for non-adherence of tuberculosis (TB) patients to DOT.**Methods:** Retrospective study of TB patients by logistic regression analysis to identify risk factors for non-adherence.**Results:** Of the 1666 patients interviewed, 1108 (67%) adhered and 558 (33%) did not adhere to DOT. Of 558 patients, the risk factors associated with non-adherence were illiteracy (39%), difficulty in accessing health facility (57%), and non-government DOT centre (43%).**Conclusion:** Patients should be educated about tuberculosis and importance of DOT. All DOT centres, including Non-government DOT centres, should be made more accessible and patient-friendly. [*Indian J Tuberc* 2007; 54:66-70]**Key Words:** TB, Non-adherence, DOT**INTRODUCTION**

DOTS (Directly Observed Treatment, Short-course), strategy in TB control has considerably improved the quality of diagnosis and treatment outcome globally. In India, DOTS was implemented since 1993 for effective management of TB treatment<sup>1</sup>. The most important component of DOTS is to ensure patient's adherence to treatment by giving every dose under direct observation. Treatment compliance may be a problem due to poor awareness of TB including treatment. Non-adherence to treatment has been recognized as a major problem for cure of TB. The aim of this study was to assess the extent of adherence to treatment under DOT during intensive phase (IP) of treatment in a rural area. We attempted to identify risk factors responsible for non-adherence to DOT.

**METHODS**

It is a retrospective study from a rural TB unit (TU) with a population of 5,80,000 in Tiruvallur district, South India. The study area includes 209 villages and nine urban clusters scattered across approximately 200 km<sup>2</sup>. The DOTS strategy was

implemented in this area since May 1999<sup>2</sup>. There are 17 governmental health facilities (HFs) participating in the programme and of these, seven offer diagnostic facilities for sputum examination. All the patients diagnosed with TB at one of these HFs are given DOT in accordance with RNTCP policies<sup>1</sup>. Every dose of treatment is to be directly observed during intensive phase (IP) and at least first of the three doses is to be directly observed during continuation phase.

During 2001-03, 3009 TB patients were registered for treatment under DOTS at the HFs in this area. Among these patients, 1319(43.8%) were new smear-positive cases, 388 (12.9%) were treated smear-positive cases and the remaining were smear-negative cases. Trained field staff interviewed 2722 (90%) patients at their residence and collected information on socio-economic demographic profile, whether they took treatment under supervision, difficulties in taking treatment under DOT and using a semi-structured questionnaire. The data on socio-economic demographic profile was collected within a week of starting the treatment and the treatment profile at the end of the IP. The study population included 1108 (41%) who adhered to DOT and 558

Tuberculosis Research Centre, Chennai

**Correspondence:** Dr. P.R. Narayanan, Director, Tuberculosis Research Centre (ICMR), Mayor V.R. Ramanathan Road, Chetput, Chennai - 600 031; Ph: 91 044 28369600; Fax: 91 044 28362528; Email: [prnarayanan@trcchennai.in](mailto:prnarayanan@trcchennai.in)

(20%) who did not adhere to DOT. The remaining 1056 (39%) who adhered to DOT partially were excluded for the analysis initially but later included in the adherence group and compared the results.

For this study, adherence to treatment is

defined as the patient treated always under supervision as reported by the patient at the time of interview. Non-adherence means that patient is never under supervision. Partially adherence means that patient is neither on always under supervision nor never under supervision.

**Table 1:** Risk factors for non- adherence of TB patients registered under a DOTS programme in a rural area, south India

| Factors   |                | No of patients | Not adherence to DOT (%) | OR C.I              |
|---|----------------|----------------|--------------------------|---------------------|
| <b>Sex</b>  | Female         | 485 (29)       | 153 (32)                 | 1.13 (0.90, 1.43)   |
|   | Male           | 1181 (71)      | 405 (34)                 |                     |
| <b>Age (years)</b>                                | ≤ 45           | 1022 (61)      | 327 (32)                 | 1.19 (0.96, 1.47)   |
|   | > 45           | 644 (39)       | 231 (36)                 |                     |
| <b>Education<sup>+</sup></b>                      | Illiterate     | 652 (40)       | 254 (39)                 | 1.47 (1.19, 1.83)** |
|   | Literate       | 970 (60)       | 293 (30)                 |                     |
| <b>Occupation<sup>+</sup></b>                     | Unemployed     | 589 (36)       | 200 (34)                 | 1.02 (0.82, 1.27)   |
|   | Employed       | 1033 (64)      | 347 (34)                 |                     |
| <b>Smoking<sup>+</sup></b>                        | Yes            | 688 (42)       | 245 (36)                 | 1.16 (0.94, 1.43)   |
|   | No             | 934 (58)       | 302 (32)                 |                     |
| <b>Alcoholism<sup>+</sup></b>                     | Yes            | 508 (31)       | 167 (33)                 | 1.06 (0.84, 1.33)   |
|   | No             | 1114 (69)      | 380 (34)                 |                     |
| <b>Difficulties in accessing HF<sup>+</sup></b>   | Yes            | 145 (9)        | 83 (57)                  | 2.96 (2.06, 4.24)** |
|   | No             | 1511 (91)      | 471 (31)                 |                     |
| <b>DOT centre<sup>+</sup></b>                     | Government     | 908 (55)       | 234 (26)                 | 2.14 (1.73, 2.65)** |
|   | Non Government | 757 (45)       | 323 (43)                 |                     |
| <b>DOT interfering daily activity<sup>+</sup></b> | Yes            | 136 (8)        | 57 (42)                  | 1.49 (1.03, 2.16)*  |
|   | No             | 1528 (92)      | 499(33)                  |                     |
| <b>Loosing wages<sup>+</sup></b>                  | Yes            | 88 (5)         | 25 (28)                  | 1.28 (0.78, 2.12)   |
|   | No             | 1576 (95)      | 531 (34)                 |                     |
| <b>Need escort DOT centre<sup>+</sup></b>         | Yes            | 98 (6)         | 31 (32)                  | 1.09 (0.69,1.73)    |
|   | No             | 1566 (94)      | 525 (34)                 |                     |
| <b>Problem in taking drugs</b>                    | Yes            | 856 (51)       | 293 (34)                 | 1.07 (0.87, 1.32)   |
|   | No             | 810 (49)       | 265 (33)                 |                     |
| <b>Cases</b>                                      |                |                |                          |                     |
| New smear positive                                |                | 709(42)        | 229(32)                  | 1.86 (1.27, 2.75)** |
| Smear negative                                    |                | 746(45)        | 286(38)                  | 2.43(1.66, 3.56)**  |
| Re treatment                                      |                | 211(13)        | 43(20)                   |                     |

\* P<0.05, \*\* P<0.01

<sup>+</sup> The number of patients is less than 1666 due to the non-availability of all patients at the time of interview within a week after treatment started.

**Table 2:** Results of the logistic regression analysis of factors for non-adherence of TB patients registered under a DOTS programme in a rural area, South India

| Factors                       | Regression co-efficient | S.E.  | P-Value | AOR   | 95% C.I.       |
|-------------------------------|-------------------------|-------|---------|-------|----------------|
| Illiteracy                    | 0.286                   | 0.111 | <0.05   | 1.331 | (1.070, 1.655) |
| Difficulties in accessing HFs | 1.104                   | 0.186 | <0.001  | 3.016 | (2.095, 4.343) |
| Non-Government DOT Centre     | 0.745                   | 0.110 | <0.001  | 2.106 | (1.698, 2.613) |
| Re-treatment cases            | 0.829                   | 0.212 | <0.001  | 2.291 | (1.512, 3.471) |
| New smear positive cases      | 0.270                   | 0.114 | <0.05   | 1.309 | (1.048, 1.638) |

Data were scrutinized and entered twice in order to ensure accuracy, corrected for discrepancy and missing information. Univariate analysis was performed and the Chi-square test was used to test the difference in proportions of socio-economic, demographic variables and information related to DOT. The level of statistical significance was defined as  $P < 0.05$ . The variables found to be significant by univariate analysis were included in a model with cases as the dichotomous variable. Stepwise logistic regression was performed and adjusted odds ratios (AOR) and 95% confidence intervals (CI) were estimated.

## RESULTS

The socio-demographic and economic characteristics of the patients included in the study are summarized in Table-1. Among the study population of 1666 TB patients registered under DOTS programme, 1181 (71%) were males, 644 (39%) were aged 45 years or more, 652 (39%) were illiterate and 589 (35%) were unemployed. The life style indicators for the patients were: 688 (41%) smokers and 508 (31%) alcoholics.

Overall, 1108 (67%) TB patients reported to have taken the treatment always under observation of DOT providers during IP. The non-adherence rate was higher among

illiterates than literates (39% vs 30%; OR=1.47; 95% CI: 1.19-1.83;  $P < 0.001$ ). Similarly, a higher proportion of non-adherence was associated with difficulties reported by patients as compared to those reported without difficulties in accessing HFs; (57% vs 31%; OR=2.96 (2.06-4.24);  $P < 0.001$ ); non-governmental DOTS centers; (43% vs 26%; OR=2.14 (1.73-2.65);  $P < 0.001$ ); and DOT interfering their daily activities; (42% vs 33%; OR=1.49 (1.03-2.16);  $P < 0.05$ ). In addition, the adherence was higher among new smear positive cases compared to re-treatment cases; (32% vs 20%; OR = 1.86 (1.27, 2.75);  $p < 0.005$ ). Similarly the adherence was higher among smear negative cases compared to re-treatment cases; (38% vs 20%; OR = 2.43 (1.66, 3.56);  $p < 0.001$ )<sup>68</sup>. It was found that illiteracy; difficulties in accessing HFs; non-governmental DOT centers; new smear positive cases and re-treatment cases were the independent risk factors for non-adherence to DOT after adjusting for confounding factors (Table-2). When patients who reported to have partially adhered to treatment were combined with those always under DOTS, the risk factors were found to be similar in univariate analysis except for “losing wages” was an additional risk factor and the factor “DOT interfering their daily activities” was found to be non significant. In multivariate analysis, “losing

wages” was identified an additional independent variable.

## DISCUSSION

The main findings of this study were 67% of TB patients reported to have adhered to DOT during IP and non-adherence of patients to treatment were associated with illiteracy, difficulties in accessing to HFs and treatment from non-governmental DOT centers, new smear positive cases and re-treatment cases. Lack of finance and distance from the patient’s residence to the HFs were the reasons reported by the patients for non-adherence to treatment (not tabulated). The reason for a significant proportion of the illiterate patients not adhered to treatment could be due to lack of knowledge about the importance of treatment under supervision. The study<sup>3</sup> conducted in Pakistan reported that illiteracy has link to the non-adherence with treatment and cure. Illiteracy was highly prevalent among the majority of the TB patients and 71% of the non-adherence cases were illiterate. Education and health awareness have strong repercussions for the sustainability of TB care. An awareness study<sup>4</sup> of TB and attitude towards DOTS among randomly selected patients belonging to low socio-economic group at one DTC, South India has reported that they preferred treatment from governmental institutions due to financial reasons and all the patients had a fairly good knowledge of treatment but none about DOTS, despite 100% literacy achieved in that area a decade ago. The activities of DOTS were decentralized at the community level and patients can take treatment closer to their residence making DOTS more accessible to them. However, in our study, 57% reported to have not adhered to treatment due to difficulties in accessing HFs.

The problems related to non-adherence of TB patients to treatment have been reported elsewhere in the country. An operational study<sup>5</sup> conducted in Delhi, during the introduction of DOTS, with patient’s non-participation has identified many problems related to patients as well as health staff. A study<sup>6</sup>, during 1999-2000, in southern Thailand where the DOTS strategy was implemented to

compare practice of actual DOTS and sustainability of different DOT providers has demonstrated that to increase the coverage of actual DOT, strategies are needed to maintain health personnel as DOT observers and to promote actual DOT among family members as observers. However, promoting family DOT providers is not advocated in India<sup>7</sup>. The results from another study<sup>8</sup> on adherence to TB treatment in Ntcheu district, Malawi, suggested that decentralized care is feasible and that the guardians and health workers can supervise the treatment during the IP. The study<sup>9</sup> carried out in Hong Kong in 2000, baseline socio-demographic and clinical characteristics were correlated with adherence to DOTS and found that geographical inconvenience was the prime reason among a significant proportion of patients failed to stay on DOTS.

About 1000 patients adhered to DOT partially were excluded for analysis initially due to the inability to ascertain the extent of adherence to DOT among these patients. However, when these patients were included along with the patients who were always under DOTs, the findings on the risk factors were more or similar. However, the proportion of patients adhered to treatment always under supervision could not be ascertained. This is a limitation of the study as it may not be possible for many TB patients to adhere to DOT 100%.

**In conclusion, the present RNTCP should develop Information, Education, Communication package for the target group of patients. Patient’s problems in accessing to treatment need to be identified and alleviated and the non-governmental DOT centres should be more accessible and patient-friendly.**

## ACKNOWLEDGEMENTS

The authors are grateful for the assistance and cooperation of the State Tuberculosis Officers of the Tamil Nadu State Government, the Joint Director of Health, the Deputy Director Tuberculosis, the Deputy Director Health Services and all the medical and paramedical staff including treatment observers who participated in this work. We thank the patients who have cooperated for the interview.

This report was funded in part by a grant from the United States Agency for International Development provided through the World Health Organization.

## REFERENCES

1. Khatri G.R, Frieden T.R. The status and prospectus of tuberculosis control in India. *Int J Tuberc Lung Dis* 2000; **4**: 193-200.
2. Santha T, Garg R, Frieden T.R, Chandrasekaran V, Subramani R, Gopi P.G, Selvakumar N, Ganapathy S, Charles N, Rajamma J, Narayanan PR. Risk factors associated with default, failure and death among tuberculosis patients treated in a DOTS programme in Tiruvallur District, South India, 2000. *Int J Tuberc Lung Dis* 2002; **6(9)**: 780-788.
3. Ibrahim Khan. Assessing adherence and its determinants among TB patients. Chapter 4. <http://www.bieson.ub.uni-bielefeld.de/volltexte/2003/332/pdf/06kapitel4.pdf>
4. Sukumaran P, Venugopal K.P, Rejoy Simon Manjooran. A Social study of compliance with DOTS. *Indian J Tuberc* 2002; **49**: 205-207.
5. Jaiswal A, Singh V, Ogden J.A, Porter J.D.H, Sharma P.P, Sarin R, Arora V.K, Jain R.C. Adherence to tuberculosis treatment: lessons from the urban setting of Delhi, India. *Tropical Med & Int Health* 2003; **8(7)**: 625-633.
6. Punggrassami P, Johnsen S.P, Chonguvivatwong V, Olsen J, Sorensen H.T. Practice of directly observed treatment (DOT) for tuberculosis in southern Thailand: Comparison between different types of DOT observers. *Int J Tuberc Lung Dis* 2002; **6(5)**: 389-395.
7. Managing the Revised National Tuberculosis Control Programme in your area: A Training Course Modules 1-4, Central TB Division, Directorate General of Health Services, Ministry of Health and Family Welfare, Nirman Bhavan, New Delhi.
8. Manders A.J.E, Banerjee A, Van den Borne H.W, Harries A.D, Kok G.J, Salaniponi F.M.L. Can guardians supervise TB treatment as well as health workers? A study on adherence during the intensive phase. *Int J Tuberc Lung Dis* 2001; **5(9)**: 838-842.
9. Wong M.Y, Leung C.C, Tam C.M, Lee S.N. Directly Observed treatment of tuberculosis in Hong Kong. *Int J Tuberc Lung Dis* 2005; **9(4)**: 443-449.

## Statement about ownership and other particulars of the Indian Journal of Tuberculosis as per Form IV under Rule 8 of the Registration of Newspapers (Central) Rules 1956.

- |  |   |  |
|--|---|--|
| 1. Place of Publication  | : | New Delhi  |
| 2. Periodicity of Publication  | : | Quarterly, published in the months of January, April, July and October                               |
| 3. Printer's name, nationality   | : | Sri S.C. Goyal, Indian;<br>3, Red Cross Road,<br>New Delhi-110 001.                                  |
| 4. Publisher's name, nationality   | : | Sri S.C. Goyal, Indian;<br>3, Red Cross Road,<br>New Delhi-110 001.                                  |
| 5. Editor-in-Chief's name, nationality   | : | Dr. R.K. Srivastava, Indian;<br>3, Red Cross Road,<br>New Delhi-110 001                              |
| 6. Name and adress of individuals who own the newspaper and partners; or shareholders holding more than one percent of the total capital | : | Secretary General,<br>Tuberculosis Association of India,<br>3, Red Cross Road,<br>New Delhi-110 001. |

I, Sri S.C. Goyal, Secretary General of the Tuberculosis Association of India, 3, Red Cross Road, New Delhi-110 001, hereby declare that the particulars given above are true to the best of my knowledge and belief.

**S.C. Goyal**

On behalf of the Tuberculosis Association of India