Abstract

Context: Directly observed treatment short course (DOTS) was adopted as the strategy for the provision of treatment to increase treatment completion. Poor adherence to medication has been noted and poses a big challenge even after achieving 70% case detection and 85% cure rate. The focus remains on dealing with important reasons of default and timely retrieval of patients who interrupt the treatment. Aims: The aim of the study was to measure the noncompliance of DOTS and to determine the reason for the same among patients in rural area of Pune. Materials and Methods: An observational cross-sectional study was conducted with a study population comprising the patients who were getting treatment in November 2016 and must have completed at least 1 month of treatment in Mulshi block. The study period was from November 2016 to January 2017. All the patients were interviewed using a pretested questionnaire for their compliance. Results: The total number of patients included in the study was 88. The age was 18–70 years in which 77.3% were male and 22.7% were female. We found 71.6% new cases, and 27.3% were the previously treated patients, whereas 1.1% were multidrug-resistant patients. Among these patients, 25% were tobacco chewers and 31.8% were smokers. We found that 61.4% were compliance patients and 38.6% were noncompliance patients. Reasons given by the patients were side effects, stigma of the society, migration from one place to another, and felt better from symptoms after taking medication. Conclusion: Noncompliance in our study is high. We should take steps regarding this so that people adhere to the medication.

Keywords: Compliance, directly observed treatment short course, noncompliance, tuberculosis

INTRODUCTION

The World Health Organization (WHO) declared tuberculosis (TB) a global public health emergency in 1993 and since then intensified its efforts to control the disease worldwide. The therapeutic regimens were given under direct observation as recommended by the WHO, which has been shown to be highly effective for both preventing and treating TB, but poor adherence to anti-TB medication is a major barrier to its global control. Factors associated with patients for poor compliance reported in the pre-directly observed treatment short course (DOTS) era were relief from symptoms, adverse reactions to drugs, and domestic and work-related problems. In India, the Revised National Tuberculosis Control Program (RNTCP), using the globally recommended DOTS strategy, has been implemented in a phased manner since 1998 through the primary health-care system.

At the national level, the program has nearly achieved its twin objectives of case detection and cure rates during the second quarter of 2007, and the program has continued to achieve it at the national level during the first quarter of 2009. However, it is to be realized that even after achieving 70% case detection and 85% cure rate, we are curing 59% of patients. What about the remaining 41% of the cases in the community? By curing only 59% of patients, the goal of RNTCP cannot be achieved.[1]

Poor adherence leads to multidrug-resistant (MDR) TB and increases mortality and morbidity. Treatment adherence of TB patients is a complex multifaceted behavioral issue and needs to be understood better. Lack of a comprehensive and holistic understanding of barriers to and facilitators of, treatment

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adherence is currently a major obstacle. Direct observation and regular home visits by treatment providers are provisions to increase treatment completion under DOTS.\(^3\)

Despite the impressive gains in compliance associated with the use of DOT, noncompliance with DOT also occurs when patients fail to make themselves available for the administration of drug therapy.\(^4\)

Defaulting from the treatment has been one of the major obstacles to treatment management and an important challenge for TB control. Poor patient adherence to the treatment regimen and inability to complete it are major causes of treatment failure and of the emergence of drug resistance.\(^4\)

Defaulting from the treatment has been one of the major obstacles to treatment management and an important challenge for TB control. Hence, it is needed to find noncompliance against TB patients and the reasons behind it.

**Objectives**
The objectives of the study were to measure the noncompliance of DOTS among patients in the rural area of Pune and to determine the reasons for noncompliance in these patients.

**Materials and Methods**
A cross-sectional study was conducted in Paud TB Unit (TU), Mulshi block, Pune district, Maharashtra. The study period was from November 2016 to January 2017. After getting permission from the ethical committee from our institution and from Paud TB Unit, the information of the total registered case during the period of November 2016–January 2017 was collected. Sociodemographic data and clinical characteristics such as smear status, type of case, type of disease, category, and treatment outcome were collected from TB register. Address of the patient, treatment details such as drug regularity, the number of doses taken by the patients, and time of treatment interruption were obtained from treatment cards. Information on the patient’s literacy, occupation, and personal habits such as smoking and drinking was taken from the patient. To obtain the data, a structured form was administered. During the study, all patients were interviewed at their homes. If the patient could not be contacted in one visit, three subsequent visits were made during the study periods. The inclusion criteria of the study were patients currently registered under RNTCP and patients who were in the treatment of TB in November 2016–January 2017. The exclusion criteria of the study were transferred outpatients and expired patients. Pediatric patients were also excluded.

**Definition of noncompliance**
If the patient missed one or more medicines for consecutive 7 days at any time during the treatment period was considered as noncompliant.\(^5\)

The collected data were coded and entered in the Microsoft Excel sheet and analyzed by the Statistical Package for the Social Sciences version 25.0 software (IBM, USA). The results were presented in a tabular and graphical format. For qualitative data, various rates, ratios, and percentages (%) were calculated.

**Results**
The study was conducted among patients of Mulshi block in Pune district who were treated for TB using the standard treatment regimen of DOTS. During the study period from November 2016 to January 2017, a total of 96 patients were registered under DOTS, but a total number of patients included in the study were 88 as four were under exclusion criteria and four could not be contacted after repeated three consecutive attempts.

Table 1 shows the sociodemographic data in comparison with the compliance to treatment.

The noncompliance was noted to be highest in the age group of 18–20 years and age group of 61–70 years with 3 (60%) patients as noncompliant. Noncompliance was found in 28 (41.18%) males.

We found that compliant patients were 61.4% and noncompliant patients were 38.6%.

Table 2 shows only one patient in MDR category (CAT) who was noncompliant, CAT-II, i.e., 22 (91.67%) had noncompliance and 2 (8.33%) had compliance. In CAT-I, the compliance patients were 52 (82.53%) and noncompliant were 11 (17.47%). CAT-wise distribution was found to be significant to noncompliance to DOTS.

Table 3 shows the habits and compliance for antitubercular drugs; noncompliance was significantly more among alcoholics and smokers.

Table 4 shows the distribution of TB patients according to disclosure to family about disease and noncompliance. Eighty-one (92%) patients disclosed with the family about disease, in which 35 (43.20%) were compliant and 46 (56.80%) were noncompliant, and 7 (8%) patients did not disclose with their family, in which 3 (42.85%) were compliant and 4 (57.15%) were noncompliant that they have TB.

Figure 1 shows the reasons for noncompliance given by the patients as follows: went to another place, felt better, side effects, not present at the time of visit, stigma, and he was not sick. Fewer patients gave more than one reason for noncompliance.

**Discussion**
In the present study, the noncompliance was 60%, which is higher in the age groups of 18–20 years and 61–70 years, which is similar to a study which observed that 22.8% of patients in the >45-year age group defaulted, whereas 3.5% of patients defaulted in the <15-year age group.\(^1\) The young age group (15–34 years) had a significantly higher percentage of compliance compared to the older age group.\(^6\) The age group of 0–20 years and >60 years total number of TB patients 87 (4.6%) and 137 (4.4%) was lower than our study.\(^4\) Older
was thought to be an alternative important reason. Furthermore, the older age group may be dependent on others for availing health services due to their age.

In the present study, 77% were male and 27% were female, which is like few other studies. Similar observations were made in other studies where 63% and 64.3% were males and 37% and 35.7% were females.

In the present study, the male noncompliance (28, 41.20%) was more than female noncompliance similar to the study which observed that patients defaulted twice as common than females (18.7% of males and 9.5% of females).

The overall default rate is 7.45%. The male patients (9%) show a higher amount of default as compared with female patients (4.3%).

In the present study, 20 (22.75%) were illiterate, 32.95% >10th standard, 25% 10th passed, 7.95% >12th standard, and 11.35% college not completed, whereas in another study, it is observed that almost 50% were educated up to primary and 23% were illiterate.

The outcome was maximum in participants educated till primary 26 (30.8%), followed by illiterates 51 (21.5%).

In the present study, the occupation of the patients was farmer (16, 18.20%), housewife (14, 15.90%), laborer (18, 20.45%), private job (13, 14.77%), self-employed (14, 15.90%), and service (9, 10.99%); in a similar type of the study, it is observed that almost one-third (30.6%) of businessmen and one-fourth (25.0%) of retired and unemployed patients defaulted. The occupation-wise distribution shows that nearly 50% of patients were laborers and few from either business or government servants. The unfavorable outcome was more (93, 17.2%) in unemployed participants as compared to employed participants (128, 14.8%).

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In the present study, 63 (71.60%) patients were from CAT-I, 24 (27.27%) were from CAT-II, and 1 (1.13%) was from MDR categories similar to a study which found that 85 (19%), 65 (38%), and 36 (11%) of the patients were from CAT-I, CAT-II, and CAT-III, respectively. The treatment interruption rate was more in CAT-II, which is of a great concern. These patients are already defaulters or relapsed patients. Hence, more attention should be given to these patients. Fifty-three

patients might be neglected more and are often abandoned by the family members, while the increase of more side effects

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| Sociodemographic variables | Noncompliance (%) | Total (%) | P, df |
|----------------------------|------------------|-----------|-------|
| Age group (years)          |                  |           |       |
| 18-20                      | 3 (60)           | 5 (100)   | 0.535, 5 |
| 21-30                      | 11 (30.55)       | 36 (100)  |       |
| 31-40                      | 8 (44.45)        | 18 (100)  |       |
| 41-50                      | 6 (46.16)        | 13 (100)  |       |
| 51-60                      | 3 (27.28)        | 11 (100)  |       |
| 61-70                      | 3 (60)           | 5 (100)   |       |
| Sex                        |                  |           |       |
| Male                       | 28 (41.20)       | 68 (100)  | 0.44, 1 |
| Female                     | 6 (30)           | 20 (100)  |       |
| Education                  |                  |           |       |
| Illiterate                 | 11 (55)          | 20 (100)  | 0.19, 3 |
| School not completed       | 11 (38)          | 29 (100)  |       |
| High school completed      | 5 (22.73)        | 22 (100)  |       |
| Graduate and above         | 7 (41.17)        | 17 (100)  |       |
| Occupation                 |                  |           |       |
| Farmer                     | 6 (37.50)        | 16 (100)  | 0.528, 6 |
| Housewife                  | 5 (35.72)        | 14 (100)  | 6       |
| Laborer                    | 9 (50)           | 18 (100)  |       |
| Private job                | 5 (38.47)        | 13 (100)  |       |
| Self-employed              | 3 (21.43)        | 14 (100)  |       |
| Service                    | 3 (33.33)        | 9 (100)   |       |
| Others                     | 3 (75)           | 4 (100)   |       |

Others include government job, student, and unemployed

| Table 2: Category-wise distribution and compliance with antituberculosis treatment |
|-------------------------------|------------------|-----------|-------|
| Noncompliance (%)             | Total (%)        | P         |       |
| CAT-I                         | 11 (17.47)       | 63 (100)  | <0.001 |
| CAT-II                        | 22 (91.67)       | 24 (100)  |       |
| MDR                           | 1 (100)          | 1 (100)   |       |
| Total                         | 34               | 88        |       |

MDR: Multidrug-resistant, CAT: Category

| Table 3: Habits* and compliance to antituberculosis treatment |
|-----------------------|------------------|-----------|-------|
| Compliance            | Noncompliance    | P         |       |
| Alcoholism, yes       | 8                | 32        | <0.001 |
| Smoking, yes          | 9                | 34        | <0.001 |
| Tobacco, yes          | 20               | 29        | 0.145  |

*Multiple responses

| Table 4: Distribution of tuberculosis patients according to disclosure to the family about disease and noncompliance |
|---------------------------------------------------------------|------------------|-----------|-------|
| Compliance (%)                                               | Noncompliance (%)| P        |       |
| Yes                                                           | 49 (60.5)        | 32 (39.5) | 0.702  |
| No                                                            | 5 (71.43)        | 2 (28.57) |       |
of 74 (72%) smear-positive patients from CAT-I had defaulted during the intensive phase of treatment. Among different treatment categories, almost one-fourth patients (26.4%) of CAT-II defaulted, whereas it was 11.4% among CAT-I and 10.8% among CAT-III patients. In the present study, 32 patients were alcoholic, 34 patients were smokers, and 29 patients had a habit of tobacco. In the present study, 49 (60.5%) patients who had disclosed about their disease to their family were compliance compared to 32 (39.5%) who had not disclosed about the disease to their family and were found to be noncompliant. It can be thus inferred that family might be helping and guiding the patient to remain compliant to the treatment. A similar study found that 271 (28%) alcohol users had a higher default rate (10.3%) compared with 279 (13%) nonusers (4.6%) which was statistically significant. We noticed the commonest reason was that the patients had gone out to other places. This indicates poor tracking of patients when they move out of TB Unit (TU) area or village due to any reason.

Reasons for default given by the patients in other studies were as follows: drug-related problems such as nausea, vomiting, and giddiness (59, 42%); migration (41, 29%); relief from symptoms (28, 20%); work-related problems (21, 15%); consumption of alcohol (21, 15%); treatment from other private or public health facility (19, 13%); domestic problems (11, 8%); stigma (4, 2%); and too ill to attend (6, 4%). Old age, other illnesses, inconvenient DOT, and dissatisfaction with treatment center and DOT provider were included as other reasons given by 22 (16%) patients. Majority of patients gave multiple reasons for default.

The treatment provider should counsel the patients about the importance of the treatment and help patients to encounter problems/difficulties for better compliance.

**Conclusion**

Noncompliance was found to be quite high. Urgent steps should be taken curb noncompliance as the country aims to eliminate TB. This aspect needs to be looked upon with priority.

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Nil.

**Conflicts of interest**

There are no conflicts of interest.

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