

Study of Non compliance to Directly Observed Treatment Short-course (DOTS) at a tertiary hospital in Dhule district (Maharashtra)

Madhukar Pawar^{1*}, Ashish Raj², Gauri Kulkarni³, Sunil Murlidhar Patil

¹Assistant Professor, Department of Community Medicine, A. C. P. M. Medical College and Hospital Dhule, Maharashtra, India

²Associate Professor, Department of Community Medicine, A. C. P. M. Medical College and Hospital Dhule, Maharashtra, India

³Professor and HOD Department of Respiratory Medicine, A. C. P. M. Medical College and Hospital Dhule, Maharashtra, India

⁴Statistician cum Assistant Professor, Department of Community Medicine, A. C. P. M. Medical College and Hospital Dhule, Maharashtra, India

Received: 27-10-2021 / Revised: 05-12-2021 / Accepted: 15-01-2022

Abstract

Background: India has been engaged in TB control activities for more than 50 years. Yet TB continues to be severest health crisis. TB kills an estimated 480000 Indians every year and more than 1400 per day. Tuberculosis is a preventable & curable communicable disease requiring prolonged treatment. The therapeutic regimens recommended by WHO and used in India, under National Tuberculosis Elimination Programme (NTEP) have been shown to be very effective for both preventing and treating tuberculosis. But poor compliance to treatment is a major barrier to its control and cause for drug resistance. **Study objective:** Study objective was to find out extent and causes of non-compliance to DOTS at a tertiary hospital. **Material and Methods:** Present study was cross sectional study. Using purposive sampling method all 112 sputum positive pulmonary tuberculosis patients, registered from January 2020 to December 2020 in the DOTS centres under department of Respiratory Medicine, A. C. P. M. Medical College and Hospital, Dhule (Maharashtra) India, were included in study. Age less than 18 years and drug resistant cases were excluded. The information was obtained from treatment cards of patients. Information of non-compliant was further elicited from the patients/DOTS providers. A criterion for non-compliance (Lost to follow up) was patient missed treatment for one month or more at any time during the treatment period. **Results:** During study period, total 112 cases were enrolled. In present study non-compliance was observed in 9 cases (8.03 %). In non-compliant cases, majority were from 31-40 year age group (33.34 %), male (66.67%), educated up to 12th standard (44.45 %), housewives (22.22 %), labourer (33.34 %) by occupation, belonging to Kuppaswamy's socioeconomic class V (44.45 %), living alone/with friends (11.11 %), married (77.78 %). Among non-compliant cases other factors such as alcohol consumption (22.22 %), smoking (33.33 %) & family history of TB (11.11 %) were noted. Among non-compliant cases, majority were newly diagnosed (77.78 %) followed by previously treated (22.22 %). Factors observed for non-compliance were patients feeling better so no need to continue treatment (44.45 %), side effects of drugs (22.22 %), migrated to other places (22.22 %), & fear of social stigma (11.11 %) **Conclusion:** In spite of one to one counseling at treatment initiation and retrieval action during follow up, non-compliance was observed in 9 cases (8.03%). Associated factors like male sex, young age, previous treatment and causes of non compliance like stopping treatment after feeling better, intolerance to anti TB drugs, migrating to other places and fear of stigma suggests improvement in health education to patient and family members, stringent follow up by healthcare providers, and use of newer treatment tracking methods.

Keywords: Non-compliance, Lost to follow up, DOTS, TB treatment, healthcare provider, TB treatment adherence.

This is an Open Access article that uses a funding model which does not charge readers or their institutions for access and distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>) and the Budapest Open Access Initiative (<http://www.budapestopenaccessinitiative.org/read>), which permit unrestricted use, distribution, and reproduction in any medium, provided original work is properly credited.

Introduction

India has been engaged in TB control activities for more than 50 years. Yet TB continues to be severest health crisis. TB kills an estimated 480000 Indians every year and more than 1400 per day[1]. Tuberculosis is a preventable & curable communicable disease requiring prolonged treatment. The therapeutic regimens recommended by WHO and used in India, under National Tuberculosis Elimination Programme (NTEP) have shown to be very effective for both preventing and treating tuberculosis. But poor adherence to treatment is a major barrier to its control and cause for development of drug resistance.

Obtaining high compliance levels in the population will reduce morbidity and mortality due to tuberculosis. Treatment administered under the supervision or direct observation of a trained professional from initiation of treatment to cure, has become a key element leading to successful DOTS[2]. The long duration of the treatment, which needs to continue even after apparent clinical recovery, is one of the main reasons for patient non-completion of their courses of treatment. For patients taking standard first-line tuberculosis treatment, missing 10% or more of their doses increases the risk of relapse six-fold[3]. A modeling study suggests that, reducing missed doses could have larger epidemiological impact on reducing TB incidence[4]. The few previous Indian studies have identified clinical (medication effects) [5,6], male gender[7] symptom improvements[5], psychological (alcohol use)[5,8], stigma[56], migration[5], factors responsible for non compliance

Material and methods

Study objective was to find out extent and causes of non-compliance to DOTS at a tertiary hospital. Present study was cross sectional

*Correspondence

Dr. Madhukar Pawar

Assistant Professor, Department of Community Medicine, A. C. P. M. Medical College and Hospital Dhule, Maharashtra, India

E-mail: drmadhukarpawar@gmail.com

study. Approval was obtained from institutional ethical committee. Written informed consent was obtained from patients. Using purposive sampling method all 112 sputum positive pulmonary tuberculosis patients, registered from January 2020 to December 2020 in the DOTS centres under department of Respiratory Medicine, A. C. P. M. Medical College and Hospital, Dhule (Maharashtra) India, were included in study. All 112 TB cases were put on 2HRZE, 4HRE fix drug combination (FDC) daily regimen. Age less than 18 years and drug resistant cases were excluded. The information was obtained from treatment cards of patients. Information of non-compliant was further elicited from the patients/DOTS providers. Criteria for noncompliance (Lost to follow up) was patient missed treatment for one month or more at any time during the treatment period. Information regarding socio demographic data (age, gender, address of the patient, literacy, occupation, and personal habits such as smoking and drinking) and clinical characteristics such as smear status, type of case, type of disease, treatment details (drug regularity, the number of doses taken by the patients), time of treatment interruption and treatment outcome was collected in predesigned-pretested proforma. Patients who defaulted on treatment were further traced in the community and interviewed thoroughly regarding

reasons of default. Statistical analysis was done using descriptive statistics.

Results

During study period, 112 cases were enrolled & completed study. Majority of cases were from 31-40 years age group (35.72%), male (67.86%), educated up to 12th standard (43.75%), housewives (20.54%), farmer (18.75%), labourer (18.75%) by occupation, belonging to Kuppuswamy's socioeconomic class IV (40.18%), living with family (91.96%), married (60.71%). Among cases other factors such as alcohol consumption (18.75%), smoking (27.68%) & family history of TB (9.82%) were noted.

In present study non-compliance was observed in 9 cases (08.03%). In non-compliant cases, majority were from 31-40 years age group (33.33%), male (66.67%), educated up to 12th standard (44.45%), housewives (22.22%), farmer (22.22%), labourer (33.33%) by occupation, belonging to Kuppuswamy's socioeconomic class V (44.45%), living alone/with friends (11.11%), married (77.78%). Among non-compliant cases other factors such as alcohol consumption (22.22%), smoking (33.33%) & family history of TB (11.11%) were noted. Among non-compliant cases, majority were newly diagnosed (77.78%) followed by previously treated (22.22%).

Table 1: Socio demographic distribution of subjects

Socio demographic variables	Total (n=112)	Percentage	Noncompliance (n=9)	Percentage
Age group (years)				
19-30	29	25.89	2	22.22
31-40	40	35.72	3	33.34
41-50	21	18.75	2	22.22
51-60	15	13.39	1	11.11
61-70	7	6.25	1	11.11
Sex				
Male	76	67.86	6	66.67
Female	36	32.14	3	33.33
Education				
Illiterate	3	2.68	1	11.11
Up to 7 th standard	40	35.71	3	33.33
Up to 12 th standard	49	43.75	4	44.45
Graduate and above	20	17.86	1	11.11
Occupation				
Housewife	23	20.54	2	22.22
Farmer	21	18.75	2	22.22
Labourer	21	18.75	3	33.34
Private service	16	14.28	1	11.11
Government service	6	5.36	0	0
Self employed	11	9.82	0	0
Others	14	12.5	1	11.11
Socio-economic class				
I	0	0	0	0
II	13	11.61	1	11.11
III	22	19.64	1	11.11
IV	45	40.18	3	33.33
V	32	28.57	4	44.45
Living status				
With family	103	91.96	8	88.89
Alone/with friends	9	8.04	1	11.11
Marital status				
Unmarried	29	25.89	2	22.22
Married	68	60.71	7	77.78
others (divorced /live in)	15	13.39	0	0
Other characteristics				
Alcohol consumption status	21	18.75	2	22.22
Smoking status	31	27.68	3	33.33
Family History of TB	11	9.82	1	11.11

Majority of cases were newly diagnosed (70.54%) followed by previously treated (29.46%) While among non-compliant cases, majority were newly diagnosed (77.78%) followed by previously treated (22.22%)

Table 2: NTEP Category wise distribution

NTEP Category	Total (n=112)	Percentage	Noncompliance (n=19)	Percentage
Newly diagnosed	79	70.54	7	77.78
Previously treated	33	29.46	2	22.22

At the end of duration of treatment completion, 86.61 % cases completed treatment, 79.46 % were declared cured & 8.03 % were non compliant (Left to follow up) 2.68 % were declared failure & started on another regimen or extended continuation phase depending on clinical/microbiological outcome. 3 (2.68 %) were transferred out due to personal problem.

Table 3: Distribution of study subjects according to treatment outcome.

Outcome	Total (n=112)	Percentage
Treatment completed	97	86.61
Cured	89	79.46
Failure	3	2.68
Defaulted	9	8.03
Transferred out	3	2.68
Died	0	0

Factors observed for non-compliance were patients feeling better so no need to continue treatment (44.45 %), side effects of drugs (22.22 %), migrated to other places (22.22 %). & fear of social stigma (11.11 %)

Table 4: The factors for non-compliance

Factors for non-compliance	Noncompliant patients (n=9)	Percentage
Patients feeling better so no need to continue treatment	4	44.45
Side effects of drugs	2	22.22
Migrated to other places	2	22.22
Fear of social stigma	1	11.11

Discussion

Directly Observed Treatment Short-Course (DOTS) involves four components: politically committed governments, improvement of laboratory diagnosis, supervised treatment with continuous supply of drugs and an information system to monitor and record appropriate treatment progress of patients and programs[7]. Despite improved diagnosis, treatment and prevention programs, tuberculosis (TB) remains a significant public health concern and a leading cause of mortality and morbidity worldwide, especially in developing countries[8]. Non-compliance is not only detrimental to the defaulters themselves, but overall exposes the community to increased risk. Development of acquired resistance is more common in these patients, which makes their management very difficult. Therefore, it is important to anticipate those at risk of being defaulters and make them adhere to anti-TB treatment. Studies which analyzed the reasons for non-adherence to TB treatment in RNTCP have concluded that it stems in a poor match between patients' and program's needs and priorities[9].

Previous research reported travel expenses, traveling to treatment centers, male sex, poor patient information and communication, alcoholism and homelessness as the major determinants of non adherence to anti-TB treatment[10,11].

Srivastava K et al.[12], studied 300 subjects, 41(13.67%) were non-compliant during treatment. Majority of noncompliant study subjects were aged more than 50 years (30.23%), skilled workers (29%), belonged to socioeconomic class III (22.9%), Muslims (19.36%) and educated up to high school (16.33%). The most common cause of noncompliance in the present study was symptomatic relief during treatment (44.45 %) followed by intolerance to medications (22.22 %).

Suparna B et al.[13], conducted a cross-sectional study on 538 patients receiving DOTS (I and II) regimen, factors associated with non-adherence were found to be different among the newly-diagnosed patients and all the other residual groups. Smoking during treatment and travel-related cost factors were significantly associated with non-adherence in the newly-diagnosed patients, while alcohol consumption and shortage of drugs were significant in the residual groups. An approach, targeting easier access to drugs, an ensured drug supply, effective solutions for travel-related concerns and modification of smoking and alcohol related behaviors are essential for treatment adherence.

Maseer Khan[14] studied, newly diagnosed sputum smear positive TB cases (174 in rural area and 107 in tribal area) under DOTS- Strategy. In the age group of 15-49 years, the treatment interruption was more in the tribal area (70.73%) when compared to rural area (64.96%). In

rural areas the most common factors for non-adherence is adverse effects (40.24%), lack of personal interest (31.70%) followed by work load (30.48%). In tribal area the most common factors for non-adherence is adverse effects (37.60%), work load (25.64%) followed by lack of personal interest (24.78%).

Aurora H[15] studied 204 newly diagnosed TB patients, 87.3% completed their treatment and 12.7% lost to follow up during treatment regime. Univariate logistics regression revealed the significant association of default with occupation, smoking, alcohol consumption, marital status and socio-economic status. It has been found that although medicines are provided free of cost, but there are many disabling factors such as low socio-economic status, family liabilities and burden of losing income from work on male patients which contribute to lost to follow up during treatment. Similar findings were noted in present study.

Pore PD et al.[16], studied 88 cases, of 18-70 years in which 77.3% were male and 22.7% were female. 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. They 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. Similar findings were noted in present study.

The most vulnerable patients faced the most difficulty in accessing and completing DOTS. Patients residing in rural areas and, taking DOTS from the government facilities had to overcome many barriers to adhere to the DOTS therapy, such as long travelling distance to DOTS centers, inconvenient timings and unfavorable attitude of the RNTCP staff, when compared to patients who took DOTS from private practitioners[17]. DOTS provider being the key person in the DOTS strategy, be trained adequately about the signs and symptoms of TB, managing side effects of the drugs under DOTS, preventive measures of the disease, proper filling of the treatment card, regular advice for continuing the treatment, motivation of the patients towards DOTS, follow-up of the sputum examination. Convenience to the patient is essential part for success of the DOTS strategy. For the success of the tuberculosis treatment, the DOTS providers must be organized based on patient's convenience rather than the convenience of the treatment providers[18].

Conclusion

In spite of one to one counseling at treatment initiation and retrieval action during follow up, non-compliance was observed in 9 cases (8.03%). Though the non-compliance was lower as compared to other studies, it continued 30 years after introduction of DOTS strategy.

Associated factors like male sex, young age, previous treatment and causes of non compliance like stopping treatment after feeling better, intolerance to anti TB drugs, migrating to other places and fear of stigma suggests improvement in health education to patient and family members, stringent follow up by healthcare providers, and use of newer treatment tracking methods.

References

1. Central TB Division, Directorate General of Health Services, Ministry of Health & Family Welfare, Nirman Bhavan, New Delhi.(2017) National Strategic Plan for Tuberculosis Elimination 2017-2025. Revised National Tuberculosis Control Programme.p5
2. World Health Organization (2002) an expanded DOTS frame works for effective tuberculosis control: Stop TB Communicable Diseases. Geneva, Switzerland.
3. Arinaminpathy N, Chin DP, Sachdeva KS, et al Modelling the potential impact of adherence technologies on tuberculosis in India. *Int. J Tuberc Lung Dis* 2020;24:526
4. Mittal C, Gupta SC; Noncompliance to DOTS: How it can be decreased. *Indian J Community Med.* 2011;36(1):27–30.
5. Al-Orainey I, Alhedaithy MA, Alanazi AR, Barry MA, Almajid FM. Tuberculosis incidence trends in Saudi Arabia over 20 years. *Ann Thorac Med* 2013;8:148–52.
6. Basa S, Venkatesh S. Study on default and its factors associated among tuberculosis patients treated under DOTS in Mayurbhanj District Odisha. *J Health Res Rev* 2015;2:25.
7. Kulkarni P, Akarte S, Bhawalkar J, et al. Non adherence of new pulmonary tuberculosis patients to anti-tuberculosis treatment. *Ann.Med Health Sci Res* 2013;3:67-74
8. Alqahtani S, Kashkary A, Asiri A, Kamal H, Binongo J, Castro K, et al. Impact of mobile teams on tuberculosis treatment outcomes, Riyadh Region, Kingdom of Saudi Arabia, 2013–2015. *J Epidemiol Global Health* 2017;7:S29–33.
9. Jaiswal A, Singh V, Porter JDH, Sharma PP, Sarin R, et al. Adherence to tuberculosis treatment : lessons from the urban setting of Delhi. *India Trop Med Int Heal.* 2003;8(7):625–33.
10. Naing NN, D'Este C, Isa AR, Salleh R, Bakar N, Mahmud MR. Factors contributing to poor compliance with anti-TB treatment among tuberculosis patients. *Southeast Asian J Trop Med Public Health* 2001; 32(2): 369-82.
11. O'Boyle SJ, Power JJ, Ibrahim MY, Watson JP. Factors affecting patient compliance with antituberculous chemotherapy using directly observed treatment, short-course strategy (DOTS). *Int J Tuberc Lung Dis* 2002; 6(4): 307-12.
12. Srivastava K, Gupta A, Saxena R, Sharma RP, Midha T. A study on non-compliance in tuberculosis cases towards the directly observed treatment short course under RNTCP in Kanpur Nagar. *Int J Community Med Public Health* 2017;4:4485-9
13. Suparna Bagchi, GuirishAmbe, Determinants of Poor Adherence to Anti-Tuberculosis Treatment in Mumbai, India, *International Journal of Preventive Medicine*, 2010;1(4):9
14. Maseer Khan, Manohar Mogili, Factors associated with non-compliance of directly observed treatment-short course for tuberculosis in a rural and a tribal village of Andhra Pradesh. comparative study, *Int J Cur Res Rev*, 2013;5(8):9
15. Aurora Heemanshu and Kapoor Satwanti, Determinants of lost to follow up during treatment among tuberculosis patients in Delhi, *International Journal of Medical Research & Health Sciences*, 2016, 5, 1:145-152
16. Pore PD, Kumar A, Farooqui IA. Noncompliance to directly observed treatment short course in Mulshi block, Pune district. *Indian J Community Med* 2020;45:291-4.
17. Yellappa V, Lefèvre P, Battaglioli T, Narayanan D, Van der Stuyft P. Coping with tuberculosis and directly observed treatment: a qualitative study among patients from South India. *BMC Health Serv Res.* 2016 Jul 19;16:283.
18. Toman K. What are the keys to cure? In: Frieden T, editor. *Toman's tuberculosis: Case detection, treatment and monitoring*

– questions and answers. Second edition, Geneva: WHO, 2004:260-62

Conflict of Interest: Nil

Source of support: Nil