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Factors responsible for default among patients under the revised national tuberculosis control programme

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Abstract---Tuberculosis (TB) is an infectious disease caused by bacillus *Mycobacterium tuberculosis*. It infects the lungs and causes pulmonary tuberculosis. But it can affect any organ in the human body. Defaulting from treatment has been one of the major obstacles to treatment management and an important challenge for tuberculosis control programmes. Defaulting from therapy is the main reason for its prevalence in our society, leading to relapse and multi-drug resistance TB cases. This study has been done to determine the causes of default among patients undergoing treatment under the Revised National Tuberculosis Control Programme (RNTCP) and their rectification.

Keywords---TB, Default, RNTCP

Introduction

Tuberculosis (TB) is an infectious disease caused by bacillus *Mycobacterium tuberculosis*. It infects the lungs and causes pulmonary tuberculosis. But it can affect any organ in the human body. TB cases show an increasing trend throughout the world. According to the global TB report 2021, the contribution of TB cases from different areas was South-East Asia (43%), Africa (25%) and the Western Pacific (18%), Eastern Mediterranean (8.3%), the Americas (3.0%) and Europe (2.3%). The thirty most TB burden countries resulted in 86% of all calculated incident cases worldwide. Eight countries resulted in two-thirds of the total global TB cases: India (26%), China (8.5%), Indonesia (8.4%), the Philippines

(6.0%), Pakistan (5.8%), Nigeria (4.6%), Bangladesh (3.6%) and South Africa (3.3%). WHO brought the concept of a revised strategy based on Directly Observed Treatment, Short-Course (DOTS) worldwide in 1993 to control the increasing cases of TB.^{1,2,3,4} The target of RNTCP was to achieve a cure rate of more than 85% among new smear-positive TB patients and to detect at least 70% of those cases in society.⁵ DOTS has resulted in a better treatment success rate in several developing countries. But an effective chain of robust healthcare facilities with a skilled workforce is paramount to WHO-endorsed DOTS success.^{6,7} TB cases in India are very high; it amounts to about one-fourth of worldwide incident TB cases. Defaulting from TB treatment is challenging for the tuberculosis control programme.^{8,9,10} Defaulting from therapy is the main reason for the high prevalence, relapse and multi-drug resistance cases. By the RNTCP guidelines, the default rate should be below 5%.¹¹ This study has been performed to determine the causes of default from treatment under RNTCP, advocating rectifying the problems in management and rehabilitation.

Method

The primary and secondary objectives were to study the causes for default from treatment under the RNTCP and to assess the default rate among patients on therapy under RNTCP.

Setting

The study was conducted on patients registered under RNTCP at Sarojini Naidu Medical College (SNMC), Agra, India.

Period

The study was carried out from April 2014 to October 2015. In this study, a pre-tested questionnaire was used. A defaulter is a patient who has not taken anti-tuberculosis drugs consecutively for two months or more after taking treatment for at least one month after registration under RNTCP.

Data Collection

The patients registered under RNTCP at SNMC, Agra, from April 2014 to March 2015 were enrolled in the study and followed up until September 2015. Informed consent was taken from the patients before enrolment in the study. A pretested questionnaire has been used for socio-demographic details, including age, sex, marital status, family size, family income, educational status, occupational status, religion, and housing. Treatment-related factors like transportation mode, time is taken to reach the DOTS centre, drug administration under supervision, and distance to the DOTS centre were also documented. Determinants which have been significant contributors to default, along with subject recruitment, are shown in Fig.1.

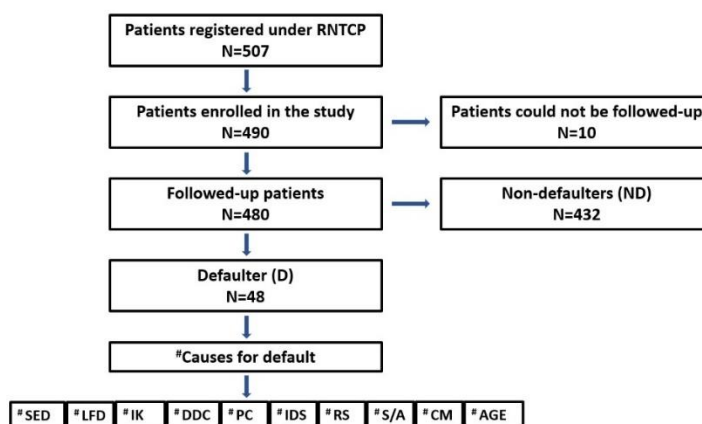


Figure 1. Methodology flowchart for the recruitment of subjects

Table 1
Abbreviations used in Figure 1

#Abbreviation	Parameter
SED	Side effects of drugs
IK	Inadequate knowledge
DDC	Distance to DOTS center
PC	Poor counselling
IDS	Irregular drug supply
RS	Relief from symptoms
S/A	Smoking/Alcohol
CM	Co-morbidities
AGE	Age more than 60 years

Discussion

The DOTS administrators have a defining role in providing supervised treatment and counselling to TB patients, along with the whole spectrum of TB care like its causes, spread, symptoms, duration of treatment, cure rate and possible side effects of medication related to TB treatment. A total of 507 subjects were enrolled in this study. 490 could be interviewed; of these, 10 could not be followed up. Out of 480, 48 defaulted from the treatment. Comparative analysis between the defaulter (D) and no-defaulter (ND) was performed for the parameters mentioned in table 1. Statistically significant and other findings have been shown in table 2.

Table 2
Comparative analysis between the defaulter and non-defaulter

Cause	Defaulter (D)	Non-defaulter (ND)	P-value
SED	85.42 (41/7)	15.28 (66/366)	<0.0001
LFD	83.33 (40/8)	49.7 (215/217)	<0.0001
IK	79.17 (38/10)	59.7 (258/174)	<0.0134
DDC	75.11(36/12)	69.6 (301/131)	<0.548
PC	70.83 (34/14)	15.05(65/367)	<0.0001
IDS	47.92(23/25)	15.05(65/367)	<0.0001
RS	87.72(42/6)	77.52(335/97)	<0.159
S/A	41.67 (20/28)	9.95(43/389)	<0.0001
CM	10.42(5/43)	4.86(21/411)	<0.2017
AGE	41.11 (20/28)	30.09(130/302)	<0.1398

Observation

Among the defaulters (D), 41 out of 48 (85.42%) complained of side effects of drugs during treatment whereas, among non-defaulters (ND), 66 out of 432 (15.28%) complained of side effects of drugs (P-value <0.0001). Similar findings have been observed in some other studies.^{12,13} Side effects like nausea, vomiting, yellow discolouration of urine and skin rashes were found to be common causes for default cases in many studies. Among Defaulters, 40 out of 48 (83.33%) belonged to a family of >5 members whereas, among non-defaulters, 215 out of 432 (49.77%) belonged to a family of >5 members (P-value <0.0001). Among Defaulters, 38 out of 48 (79.17%) were not aware of TB as a disease, whereas, among non-defaulters, 258 out of 432 (59.72%) were not aware of TB in prior (P-value <0.0134).^{14,15} Among defaulters, 36 out of 48 (75.00%) resided>2km from the DOTS centre, whereas, among non-defaulters, 301 out of 432 (69.68%) resided>2km from the DOTS centre (P-value <0.548).

Results

Among defaulters, 34 out of 48 (70.83%) were not satisfied with the counselling techniques, whereas, among non-defaulters, 65 out of 432 (15.05%) were not satisfied with the counselling (P-value <0.0001). In defaulters, 23 out of 48 (47.92%) got an irregular supply of medicine at DOTS, whereas, among non-defaulters, 65 out of 432 (15.05%) got an inconsistent supply of medication at the

DOTS centre (P-value 0.0001). A family-based DOTS programme should be encouraged; a similar concept was used in a few studies.¹⁶ In defaulters, 42 out of 48 (87.72%) were noted for symptoms relief whereas, among non-defaulters, 335 out of 432 (77.52%) were indicated for symptoms relief. Among defaulters, 20 out of 48 (41.67%) were alcoholics whereas, among non-defaulters, 43 out of 432 (9.95%) were alcoholics (P-value <0.0001). Alcoholism has been recognised as a risk factor for default in patients under TB treatment and is associated with poor outcomes.¹⁷ Several studies have reported similar findings throughout the world.¹⁸ Among defaulters, 5 out of 48 (10.42%) had comorbidities like HIV (Human immunodeficiency virus)/AIDS (Acquired immune deficiency syndrome) and DM (Diabetes mellitus). In contrast, among non-defaulters, 21 out of 432 (4.86%) had comorbidities with the same comorbidities. Among the defaulters, 20 out of 48 (41.11%) were above 60 years of age, whereas among non-defaulters, 130 out of 432 (30.09%) were above 60 years of age. Comparative statistical analysis has been performed for the socioeconomic and demographic parameters between defaulters and non-defaulters, and a computational circos network diagram has been plotted, shown in figure 2,3.

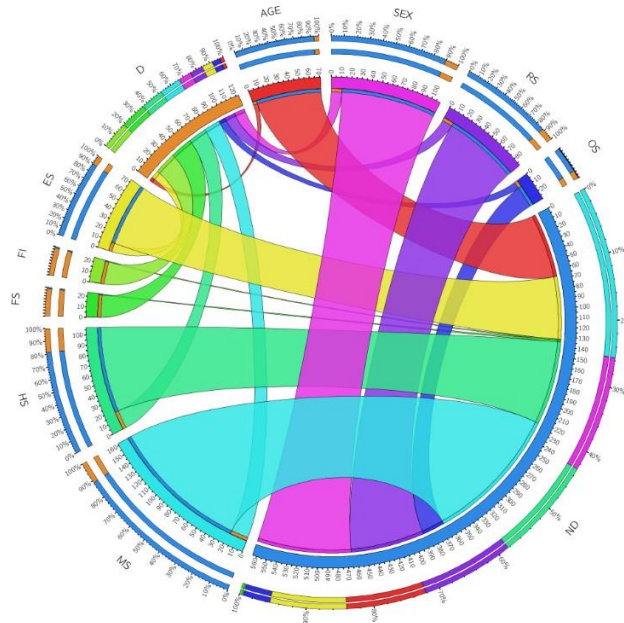


Figure 2. Circos network diagram, standard deviation (SD) values plotted for socioeconomic, demographic parameters between defaulters and non-defaulters

Parameter	D (SD)	ND (SD)
AGE	3.605	67.104
SEX	11.313	97.58
MS	17.776	144.405
FS	22.627	1.414
FI	22.627	1.414
ES	8.648	64.666
OS	6.603	22.289
RS	10.984	77.175
HS	19.052	87.469

MS: Marital status; FS: Family size; FI: Family Income; ES: Educational status; OS: Occupational status; RS: Religion status; HS: Housing status

Figure 3. Input data for the circons network diagram

Conclusion

Several studies have shown that poor delivery of knowledge and information to the patients and society culminates in default.¹² Clinical features and signs of TB patients often improve within a few months of initiating the anti-tuberculosis medication. If not adequately explained about the complete spectrum of disease and its treatment, TB patients are bound to think that the disappearance of clinical features and signs is an early indication of complete recovery. Proper counselling about TB's full spectrum must reduce the default rate.^{19,20} TB management demands a holistic and robust approach with directed counselling and motivation to the patients and the affected family.²¹ In Indian sub-continent, untreated or defaulted TB cases laterally get complicated with many other ailments like tuberculosis of the spine, which in many cases increases the patient's frailty.²²

This study has certain limitations; we could not remove the probability of recall bias, which might have occurred as the study methodology was questionnaire-based and subjective to the insight, information, and knowledge of the recruited subjects. Secondly, this study was based on a single centre; data validation and replication from other centres were not incorporated. The total default rate reported in this study was 10%. This study has identified vulnerable patients and groups having an increased risk of default, such as alcoholics, large family size, poor counselling, side effects of drugs, and irregular drug supply. Other contributing factors for default were inadequate knowledge and smoking. In this study, we have not found a positive relation between default and age of the patients, distance to the DOTS centre, relief from symptoms, and comorbidities. Early identification of potential default groups, cohorts, and individuals is vital for interrupting the vicious cycle of default in TB management. Targeted group counselling, health education, and strengthening the supply chain logistic network will help curb the default rate exponentially.

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Disclosures

Human subjects: Consent was obtained by all participants in this study. Conflicts of interest: In compliance with the ICMJE uniform disclosure form, all authors declare the following: Payment/services info: All authors have declared that no financial support was received from any organisation for the submitted work. Financial relationships: All authors have declared that they have no financial relationships at present or previously with any organisations that might have an interest in the submitted work. Other relationships: All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

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