Original Research Article

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Evaluation of revised national tuberculosis control programme in rural Puducherry

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ABSTRACT

Background: WHO estimates that annually 3 million deaths occurs due to tuberculosis and will reach to more than one billion in 2020. In India, more than 40% of population is infected. The revised national tuberculosis control programme (RNTCP) uses directly observed treatment, short-course (DOTS) therapy strategy to reduce mortality and morbidity, reduce transmission. Compliance to DOTS therapy is one of the important factors that affect the treatment outcome. Hence this study was done to assess the drug compliance rate of adults registered under RNTCP in the past one year and first three months after starting the study and to explore the factors associated with drug compliance.

Methods: A longitudinal study was done in Bahour Commune Panchayat with subjects registered under RNTCP from January 2011 to March 2012. They were followed-up by house visit, interviewed using a semi-structured questionnaire.

Results: The mean age was 44 ± 13 years, 35 (68.6%) males were illiterate. About 60 (85.7%) belong to Class IV socio-economic status; 15 (29.4%) and 33 (64.7%) of adults had smoking and alcohol intake respectively; 03 (04.3) were diabetic. The treatment compliance rates were cured 64.3% (45/70), completed 27.1% (19/70), default 2.9% (02/70), failure 5.7% (04/70).

Conclusions: Male being diseased in the productive age-group, will not only affect the health of the patient but also affect the family's economic status. Most of the males gave history of alcohol intake, for which they require constant motivation for compliance to the treatment.

Keywords: TB, RNTCP, Compliance

INTRODUCTION

Tuberculosis is a communicable disease with highest burden in India in more than 1/5th of global disease burden i.e., with an incidence of 1.98 million out of 9.4 million new cases annually. In India, more than 40% of population is infected (prevalence of infection) with *Mycobacterium tuberculosis*. It is estimated that there are 3.3 million prevalent case of all forms of TB disease (smear positive PTB, smear negative PTB and extra-

pulmonary TB). It is also estimated that about 2,76,000 people die due to TB annually in India.² The greatest burden of tuberculosis incidence and mortality in India is in adults aged 15 to 60 years, which include the most productive members of society. TB affects more men than women, but still kills more women than all causes of maternal mortality put together. The revised national tuberculosis control programme (RNTCP) was launched in India in 1997 with the basic preventive and curative strategy is the treatment of infectious TB patients until cure. The RNTCP uses the directly observed treatment,

short-course (DOTS) chemotherapy strategy, which is based on results of tuberculosis research done in India. The goal of RNTCP is to decrease morbidity and mortality due to TB and reduce the transmission of infection until TB ceases to be a major public health problem. The goal is achieved through the following objectives which are to achieve and maintain case detection rate of at least 70% among total estimated cases and to achieve and maintain cure rate of at least 85% of newly detected infectious cases (new sputum smear positive) in the population.³⁻⁵ The RNTCP with the DOTS strategy has been functioning effectively in the State of Puducherry, and as a result of which the health status of TB patients have been improved. There are multitudes of complex, inter-related social, economic and other factors that play a role in patients' adherence to the DOTS regimens. By carrying out the current study, we wanted to assess the compliance rates and to explore the factors associated with treatment compliance in rural area of Puducherry. The results would help us in assessing the factors associated with from patient's perspective during the treatment. Those factors which could not be covered by the questionnaire would be elicited by conducting indepth interviews, where the subjects enlisted the factors for treatment compliance. The results would help us in recommending the formulation of better strategies to reduce default rates among patients undergoing treatment under RNTCP. Ultimately this would contribute towards the improvement of the national TB control program.

Aim

The aim of the present study was to assess the treatment compliance rates of adult tuberculosis patients registered under RNTCP between 01 January 2011 and 31 March 2012 in rural Puducherry and to explore the factors associated with treatment compliance.

METHODS

The present study was started after getting clearance from Institutional Human Ethics Committee. This was a longitudinal study done to over a period of fifteen months from 1st January 2012 to 31 March 2013. The study was conducted in Bahour Commune Panchayat of Puducherry which falls under the field practice area of the Rural Health Training Centre of Mahatma Gandhi Medical College and Research Institute covering 15 villages with the population of 59, 430 as per 2011 census. ^{6,7} Adult TB patients from Bahour Commune Panchayat who were registered between 01 January 2011 and 31 March 2012 in the TB register constituted the study population.

Inclusion criteria

Persons of 18 years and above given informed consent and individuals already registered under RNTCP from Bahour Commune Panchayat in the past one year and the cases registered during the mentioned study period.

Exclusion criteria

Houses locked or if the patient is not present at the time of visit (maximum of 3 visits were made) and houses to which the patient had expired.

A pre-designed and pre-tested questionnaire was used which had three main sections.

Part I

Information about socio-demographic characteristics like age, sex, literacy status, occupation, monthly income and housing.

Part II

Information regarding chronic illness in the family, history of smoking, alcohol and other substance abuse.

Part III

Information about the primary symptom before diagnosing TB, place of diagnosis, source of information about RNTCP, duration of the course, regularity of treatment, whether drugs were taken under supervision and history of any side-effect during the course of treatment.

Data collection procedure

Permission was obtained from The Director Health Service, Directorate of Health and Family Welfare Services, from Mission Director, Puducherry State Health Mission and from the Tuberculosis Programme Manager, Chest Clinic, Puducherry to access the details of the registered cases of Tuberculosis from the TB register at Chest Clinic, Puducherry. The study participants were listed out from the TB register by the above mentioned selection criteria. Those patients registered from 3 PHCs were contacted personally and were invited to participate in the study, after explaining the purpose and scope of the study. Those who gave consent to participate were followed-up by house-to-house visits and were assessed by the study tools and the outcomes were measured. Between January 2011 and March 2012, there were 117 cases registered from Bahour Commune Panchayat, out of which one patient was wrongly entered in the register, as he was from another Commune, and nine patients died during the treatment. House visits were not made to those patients who died during the course of the treatment. During the house visit, either if the house was locked or if the patient was not present during that visit, that house was revisited with a maximum of 3 visits. In depth faceto-face interviews were conducted with the study subjects to elicit the required information. Treatment outcome was categorized as "positive compliance", which included patients who had completed the full course and have been declared cured and "negative compliance", which included treatment failure and defaulted patients. Patients who were registered during the mentioned study period but had expired during the data collection period were not included for further analysis of the study.

Statistical analysis

The data was entered and analyzed using Epi-Data Version 3.1. Data is being presented as percentages and ratios. To find out association between treatment outcome with socio-demographic characteristics, Chi-square test and Fisher's exact p test were used. Fisher's exact p test was used when at least one expected value was less than 1 or 20% of values were less than five. p value of less than 0.05 was considered as statistically significant.

RESULTS

Out of the 117 tuberculosis patients registered during the study period in the selected geographical location, 70 patients met the selection criteria. Hence, they were followed-up and necessary data were collected.

Socio-demographic characteristics

The mean age of the study population was 44.4±12.7 years. Out of the followed-up 70 subjects, 72.9 % were males and 27.1 % were females. Majority of males (37.3%) were from the age group 40-49 years while more than half of females (57.8%) were from the of 18-29 years age group (Table 1). 90.2% of males and 47.4% of females were married and constitute to more than three-fourth (78.6%) of the total number of subjects. About 58.6% of the participants were illiterate among which

one-third were males (68.6%) whereas 36.8% of females were graduates.

Table 1: Age-sex distribution of the study population.

Age group (in years)	Male N (%)	Female N (%)	Total N (%)
18-29	03 (05.9)	11 (57.8)	14 (20.0)
30-39	05 (09.8)	03 (15.8)	08 (11.4)
40-49	19 (37.3)	01 (05.3)	20 (28.6)
50-59	16 (31.3)	01 (05.3)	17 (24.3)
60 and above	08 (15.7)	03 (15.8)	11 (15.7)
Total	51 (72.9)	19 (27.1)	70 (100)

About 62.7% of males worked for daily wages and 52.6% of females are housewife. A vast majority (94.3%) of the study population were living as nuclear families and 52.9% of the study population were living in semi-pucca houses. About 85.7% of subjects belonging to Class IV and none of them were in Class V according to Modified B. G. Prasad's classification.

Compliance profile of the study population

Among males, 29.4% were smokers and 64.7% consumed alcohol. None of the female study subjects reported to have the habit of smoking or alcohol intake. None of the study subjects reported any history of substance abuse. Out of the 70 subjects, 92.9% received their DOTS drugs from PHC. There were 74.3% patients under category-I, 12.9% patients were in category-ii and 12.8% were under others category (non-DOTS) (Table 2).

Table 2: Category-wise distribution of study population.

Duration of treatment	Male	Female	Total
(Category)	N (%)	N (%)	N (%)
6 months (Category I)	40 (78.4)	12 (63.2)	52 (74.3)
8 months (Category II)	09 (17.6)	00 (00.0)	09 (12.9)
12 months	01 (02.0)	07 (36.8)	08 (11.4)
Others (non-DOTS)	01 (02.0)	00 (00.0)	01 (01.4)
Total	51 (72.9)	19 (27.1)	70 (100)

Out of the total 70 subjects, 3 males were known diabetics; while 95.7% of the subjects were not aware of

their diabetic status. It was observed that among the total participants, 91.4% had positive compliance and 8.6% had negative compliance.

Table 3: Association between side effects and compliance.

	Compliance	P value			
Side effects	Positive		Negative		
	N	%	N	%	
Yes	11	17.2	4	66.7	
No	53	82.8	2	33.3	0.017
Total	64	100.0	6	100.0	

Association of socio-demographic variables with treatment outcome

It was observed that persons with reported side effects (17.2%) are said to have negative compliance (66.7%). There was significant association observed between side effects and compliance (p=0.017) (Table 3).

It was observed that subjects who reported to have side effects were said to have decreased compliance by 0.104 times. It can be appreciated in almost every 19 subjects (Table 4). It was observed that subjects who were reported to have regular intake of drugs during the treatment have an increased chance of about 4.8 times for positive compliance. This can be appreciated in every 7.3 subjects, though it was not statistically significant (Table 5).

Table 4: Binary logistic regression showing association of side effects on compliance.

	D	D Sia	E (D)	95.0% C.I. for EXP(B)		R square
В	Sig.	Exp (B)	Lower	Upper		
Side effects (yes)	-2.266	0.015	0.104	0.017	0.639	0.196
Constant	3.277	0.000	26.500		0.039	

Table 5: Binary logistic regression showing association of regularity of drug intake on compliance.

	D	Sig.	Cia Erm (D)		95.0% C.I. for Exp (B)	
ь	Sig.	Exp (B) Lower	Upper	R square		
Regular treatment (Yes)	1.576	0.103	4.833	0.727	32.125	0.073
Constant	1.099	0.178	3.000	0.727	32.123	

DISCUSSION

This study was conducted with the aim to know the treatment compliance rates among the adults registered. This study also described the factors associated with outcome of treatment among TB patients and assessed their association with socio-demographic variables.

The mean age of the study population was 44.4 ± 12.7 years, which is of higher mean when compared with the study by Manisha et al, which reported to be 29.2 ± 13.3 years of age and the number of married subjects in that study were higher in number when compared with the present study, which had 55 (78.6%). About 32% of the study subjects were illiterate, which is almost twice in the present study with 41 (58.6%). About 51.2% belonged to lower middle class, while from our study, it was observed that 60 (85.7%) of our study subjects were from Class IV (upper middle class).

There were 19 (37.3 %) of males were belonging to the age group 40-49 years and 11 (57.8 %) of females were belonging to the age group of 18-29 years., which when compared to a study done by Pradeep et al, is in older age group. According to the present study, 94.3% were belonging to nuclear type of family, which implies that the patients have a little familial support and that was also a reason for their defaulting. There were 52.9% males and 52.6% females were living in a semi-pucca house, which could have been an unfavourable condition for contact with dust and unsanitary conditions.

The results have shown that the treatment success rate (cured and completed) was 91.4%, default rate of 2.9% failure rate of 5.7%. According to RNTCP status report the case detection rate of India during 2009 was 72% and

the cure rate was around 87%, whereas from the present study, the positive compliance, which included the cured and completed patients to be 91.4%, which is well under the target of RNTCP Objectives. From this study, it was observed that there were 2 defaulters who were males, with a defaulter rate of 2.86%, and 4 failures with a failure rate of 5.71%, which when compared with the RNTCP reports of previous years is similar. ¹⁰

There were 2 defaulters from the present study, and the reasons for defaulting from the treatment regimen was reported to be alcoholism and work-related, as they have to travel long distance for their work. Similar observations were recorded in the study by Jaggarajamma et al.¹¹

In this present study, there was statistically a significant association among subjects reported with side effects (17.2%) are said to have negative compliance (66.7%). There was significant association observed between side effects and compliance (p=0.017). By binary logistic regression, those who were reported to have side effects were observed to have decreased compliance by 0.104 times and those subjects reported to have no side effects were said to have increased chances of Positive compliance by 9.6 time. This goes similar with the study done by Finlay et al.¹²

Factors associated with successful treatment compliance from in-depth interview

Relationship with the DOTS provider like auxiliary nurse mid-wives and staff nurses, motivation from family members to take regular medications, timely supply of drugs were some factors associated with successful treatment compliance.

Factors associated with default from in-depth interview

Longer duration of treatment, large pills and side-effects, alcohol intake and forgetfulness, employment as they had to travel to distant places for their work, low literacy level, lack of social support and beliefs were the Factors associated with default from in-depth interview.

CONCLUSION

The treatment outcomes and compliance rates observed in the current study were satisfactory, as per the RNTCP objectives. Majority of the study subjects were males and belong to productive age group and were illiterates with upper middle socioeconomic status. Being male and belonging to productive age group will not only affect health of the patient but also affect the family's economic status. Majority of the males in the study area gave history of regular alcohol intake, which was one of the major factors for skipping of the drugs and forgetfulness. Positive compliance was associated with female sex. Negative compliance (failure rate and default rate) was associated with male sex.

Recommendations

The compliance rates can be improved by training and motivating DOTS providers and TB workers through periodical in service sensitization and workshops towards quality care. Group sessions in the DOTS centres regarding the treatment and managing of the medication side-effects will also be helpful. Patients should be counselled and motivated with their family members about the importance of DOTS to improve compliance to the drugs. Possible support from Non-Governmental Organization, outreach campaigns in the community and health education about TB should be done can effectively combat the disease.

Limitations

Since the addresses of the registered cases were obtained from the State TB register, which had some wrong entry of data, change in name, relationship order, missing door number, and lack of contact number of the patients-some potential patients were could not be traced/included for the current study. The time-lag between default and interview was a minimum of one year, which could have resulted in a recall bias. The collected information was as told by the patients, so the elicited answers could have been a negative report by the patient.

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Conflict of interest: None declared

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