Original Article

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A Study of Treatment Compliance in Newly Diagnosed Cases of Tuberculosis under District Tuberculosis Centre of Central Maharashtra

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Abstract

Background: Tuberculosis is an old disease and has deep social impact on the society. It is an re-emergent killer disease with rise in MDR and XDR strains. DOTS strategy has had a substantial impact over past few decades. Monitoring outcome of TB treatment is very much important in evaluating the effectiveness of tuberculosis control program. Keeping in view all of these facts, it was decided to study compliance and outcome of newly diagnosed cases of Tuberculosis, subjected to short course chemotherapy regimen under DOTS. **Subjects and Methods:** The study was a prospective cross sectional study conducted in newly diagnosed cases of Tuberculosis, subjected to short course chemotherapy regimen (DOTS). Medical records of all TB patients registered from April 2020 to 31 October 2020 were reviewed. Tuberculosis types, HIV and Diabetes status, as well as treatment outcomes were categorized according to RNTEP guidelines. **Results :** Out of total 663 patients, 408 (61.53%) were males and 225 (38.47%) were females. Male to female ratio was observed to be 1.60:1. The mean age of males was 40.02 ± 14.04 and mean age of females was 36.15 ± 14.82. 57.02% patients were having pulmonary Tuberculosis and 42.98% patients were having extra pulmonary tuberculosis. Treatment outcome among total 663 patients was as follows – 288 (43.43%) patients got cured, 251 (37.85%) completed treatment, 55 (8.29%) dies, 8.76 (5.88%) were lost to follow up (defaulter) and 30 (4.52%) failed treatment. **Conclusion:** The treatment success rate of tuberculosis patients was adequate (81.28%) in relation with national targets. Again easy accessibility of healthcare services are required to further improve the compliance of TB treatment.

Keywords: Tuberculosis, Compliance.

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Introduction

As one of the signatory of the UN Millennium declaration (2000) India carries great responsibility of combating tuberculosis (TB). Presently two of every five Indians are infected with the TB bacillus.[1] More adults in India die from TB than from any other infectious disease.[2] In the view of such a high disease burden it really needs exhaustive efforts to achieve the Sustainable Development Goals.[2] Still Tuberculosis (TB) is among the top 10 causes of death worldwide.

National Tuberculosis Elimination Program (NTEP, previously known as RNTCP) decentralizes the supervision and managerial responsibilities through creation of Tuberculosis Units (TU) and Designated Microscopy Centre (DMC). RNTCP evolved as the most rapidly developing program in the world covering entire country's population. TB treatment strategy under this program is proven, cost-effective. It is a combination of technical and managerial components which quickly makes the infectious cases non-infectious and breaks the cycle of transmission. DOTS also prevent the development of MDR and XDR TB that are often fatal and more expensive to cure.[3,4]

Maintaining the quality of TB services is crucial as the program moves towards attaining high cure rate and increasing case detection. It has been observed that although all patients were recorded as having received daily regimen or directly observed treatment (DOTS), some of them did not actually receive it. Patients, who were not directly observed while consuming the drugs, were more likely to have poor treatment compliance as compared to those who had received DOTS.[5,6] Evaluation of case finding and treatment activities at all levels is important to determine actual status of the program in the

field setting.

Keeping in view all of these facts, it was decided to study compliance and outcome of newly diagnosed cases of Tuberculosis, subjected to short course chemotherapy regimen. All the cases included in the study were given short course chemotherapy and compliance was monitored according to RNTCP guidelines.

Subjects and Methods

The study was a prospective cross sectional study conducted in newly diagnosed cases of Tuberculosis, subjected to short course chemotherapy regimen, to determine the compliance to treatment.

Study Period: All the tuberculosis patient registered during the period of 1^{st} April 2020 to 31^{st} October 2020 were included in the study. The patients were followed till completion of their treatment.

Study Area: The study area was under coverage of District Tuberculosis Center (DTC), Latur, and Maharashtra.

Inclusion Criteria

All newly diagnosed cases of Tuberculosis were included in the study.

Exclusion Criteria

1. Already diagnosed cases and on treatment of Anti tubercular drugs were excluded.
2. All cases of Defaulter, Failure and Relapse were excluded.
3. All cases below 15 years of age group were excluded.

Selection of Study Population: All newly diagnosed cases of Tuberculosis and put on AKT under DOTS, during the study period were selected for the study. So out of 979 patients enrolled under the DTC during the study period, total 663 patients satisfying the inclusion criteria were included in the study. All these patients were followed up to their completion of treatment. After taking the necessary permission, the data were taken from the medical records of the patients at the District Tuberculosis Center (RNTCP case sheet, RNTCP treatment card, TB register and Nikshay software).

Statistical Analysis: Analysis was done by using percentages, Chi square test, standard error of difference between two means.[7]

Definitions in RNTCP.[8]

1. **New Case:** A patient who has never had treatment for tuberculosis or has taken anti tuberculosis drugs for less than one month.
2. **Cured :** An initially smear positive patient who has completed treatment and had negative sputum smear on at least two occasions one of which was at completion of treatment.
3. **Treatment Completed:** Sputum smear positive case who has completed treatment, with negative smears at end of initial phase but none at end of treatment. OR Sputum smear negative TB patient who has received full course of Treatment and has not become smear positive during at end of treatment OR Extrapulmonary TB patient who has received full course of treatment and has not become smear positive during or at end of treatment.
4. **Lost to follow up (Defaulted):** A patient who at any time after registration has not taken anti TB drugs for 2 months or more consecutively.
5. **Died:** Patient who died during treatment regardless of cause
6. **Failure:** Smear positive case who is smear positive at 5 months or more after starting treatment. Failure also includes a patient who was initially smear negative but who became smear positive during treatment.

Results

Above [Table 1] shows distribution of Tuberculosis patients according to age and sex. Maximum number of patients were in the age group of 25-34 years i.e. 64(28.95%), followed by 22.17% in the age group 35-44 years and least in the age group 55-64 years i.e. 06.78%. Majority of patients (69.68%) were distributed in 15-44 years age group.

Out of total 663 patients, 408 (61.53%) were males and 225 (38.47%) were females. Male to female ratio was observed to be 1.60:1. The mean age of males was 40.02 ± 14.04 and mean age of females was 36.15 ± 14.82 and this difference was not found to be statistically significant ($Z= 1.88$, $p > 0.05$).

Above [Table 2] shows distribution of pulmonary tuberculosis patients according to type of tuberculosis i.e. Pulmonary Tuberculosis and Extra Pulmonary Tuberculosis.

Out of 663 patients, 378 (57.02%) patients were having pulmonary Tuberculosis and 285 (42.98%) patients were having extra pulmonary tuberculosis. 279 (68.38%) males and 99 (38.82%) females were having pulmonary Tuberculosis. Whereas 129 (31.62%) males and 156 (61.18%) females were having extra pulmonary Tuberculosis.

[Table 3] shows distribution of pulmonary tuberculosis patients according to HIV Status. 366 (89.70%) males and 249 (97.64%) females were having negative HIV status. 42 (10.30%) males and 06 (02.36%) females were having positive HIV status.

Out of 663 Tuberculosis patients studied, Diabetes mellitus were found in 48 (7.24%) cases. Among them 33 (8.08%) were

Table 1: Distribution of Tuberculosis Patients According to Age & Sex

Age in years	Sex				Total	
	Male		Female			
	No	%	No	%	No	%
15-24	54	13.23	69	27.05	123	18.55
25-34	120	29.41	72	28.23	192	28.95
35-44	108	26.47	39	15.29	147	22.17
45-54	60	14.70	36	14.11	96	14.47
55-64	27	06.61	18	07.09	45	06.78
65+	39	09.58	21	08.23	60	09.08
Total	408	100	255	100	663	100

Table 2: Distribution of Tuberculosis Patients According to Type of Tuberculosis (Pulmonary Tuberculosis and Extra Pulmonary Tuberculosis):

Type of patients	Male		Female		Total	
	No.	%	No.	%	No.	%
Pulmonary Tuberculosis	279	68.38	99	38.82	378	57.01
Extra Pulmonary Tuberculosis	129	31.62	156	61.18	285	42.99
Total	408	100	255	100	663	100

Table 3: Distribution of Tuberculosis Patients According to HIV Status

HIV status	Male		Female		Total	
	No.	%	No.	%	No.	%
Non-Reactive (- ve)	366	89.70	249	97.64	615	92.76
Reactive (+ ve)	42	10.30	06	02.36	48	7.24
Total	408	100	255	100	663	100

Table 4: Distribution of Tuberculosis Patients According to Diabetic Status

Diabetic status	Male		Female		Total	
	No.	%	No.	%	No.	%
Non - Diabetic	375	89.70	240	97.64	615	92.76
Diabetic	33	08.08	15	05.88	48	07.24
Total	408	100	255	100	663	100

Table 5: Treatment Outcome of Pulmonary and Extra pulmonary Tuberculosis Patients

Treatment Outcome	Pulmonary Tuberculosis		Extra Pulmonary Tuberculosis		Total	
	No.	%	No.	%	No.	%
Treatment completed	72	19.04	216	75.78	288	43.43
Cured	251	66.66	NA	NA	251	37.85
Lost to follow up	14	3.70	25	8.76	39	5.88
Died	29	7.67	26	9.12	55	8.29
Failure	12	3.17	18	6.31	30	4.52
Total	378	100	285	100	663	100

N.A.= Not Applicable (cured : Applicable for Pulmonary Tuberculosis patients only.)

males and 15 (5.88%) were females.

The above table shows the Treatment outcome of all tuberculosis patients.

Out of 663 tuberculosis patients, 251 (37.85%) were cured and 288 (43.43 %) were treatment completed. 55 (8.29%) were died during course of treatment. 30 (4.52%) were treatment failure.

Out of 378 pulmonary tuberculosis patients, 251 (66.66%) were cured, 72 (19.04%) were treatment completed. Whereas out of 285 extra pulmonary tuberculosis patients, 216 (75.78%) were treatment completed.

Discussion

This study was conducted in newly diagnosed cases of Tuberculosis, subjected to short-course chemotherapy regimen, to determine the compliance to treatment.

Majority of Tuberculosis patients (69.68%) were distributed in 15-44 years age group (which is the most productive age group). This was also reported by many authors. S. L. Chadha carried out a study to determine the factors affecting compliance of DOTS, found that, out of total 693 subjects, 415 (58.8%) patients were in the age group 21-40 years.[9] R. Rajeswari carried out a study to determine the socio-economic impact of Tuberculosis on patient and family in India, observed that the mean age in study population was 37.8 ± 14.9 years and 69% were males & 84% were females.[10] V. K. Arora carried out a prospective study to determine feasibility, acceptability and efficacy of DOTS given to tuberculosis patients. He observed that the age group of 21-30 years was more affected (36.5%) followed by 11-20 years (25%). In the study subjects the ratio of males to females was 1.2:1. The males were 53.8% and females were 46.2%.[11] M. Vasantha conducted a study to estimate the survival of tuberculosis patients treated under DOTS in a rural TB unit (TU) in Tiruvallur district, South India. Vasantha observed that, out of total 3818 subjects, 2013 (53%) were in the age group 15-45 years. 2770 (73%) were males and 1048 (27%) were females.[12]

In the present study, the male patients (61.53%) outnumbered the female patients (38.47%) and the male to female ratio was 1.60:1. The male to female ratio is comparable with R. Rajeshwari (2.1:1),[10] Dheeraj Gupta (2.1:1).[13] The males were affected more than female population. These may be due to, heavy outdoor work, various types of addictions which cause more exposure to tuberculosis infection.

In the present study distribution of tuberculosis patients according to type i.e. Pulmonary Tuberculosis and Extra Pulmonary Tuberculosis shows that out of 663 patients, 378 (57.02%) patients were having pulmonary Tuberculosis and 285 (42.98%) patients were having extra pulmonary tuberculosis. In the study conducted by Tahir M observed that, corresponding proportions of PTB and EPTB cases in New Delhi were 62.4% and 37.6% respectively.[14] Md. Shamim Akhtar in his study conducted at JN Medical College at Aligarh found that, 76% were pulmonary cases and 24% were extra pulmonary cases.[15]

In the present study number of males 279 (68.38%) were having pulmonary Tuberculosis as compared with females 99 (38.82%). This may be because males are working out door for job. Addictions like smoking, tobacco are more commonly seem in males than females. Hence their exposure to tuberculosis and chance of getting pulmonary tuberculosis is more than female.

In the present study Diabetes Mellitus were found in 33 (8.08%) males and 15 (5.88%) females, whereas out of 663 tuberculosis patients, majority of patients i.e. 615 (92.76%) were having negative HIV status and 48 (7.24%) were having positive HIV status. Similar results were observed by S. Rajasekaran. He carried out a study to determine clinical manifestations and the modes of presentation of Tuberculosis cases in Govt. Hospital, Chennai. In his study, HIV infection was detected in 39 (4.26%) of the total 915 tuberculosis patients screened.[16] S. K. Jain carried out a sentinel surveillance study to determine the prevalence of HIV infection among newly diagnosed untreated tuberculosis patients in Delhi. In his study, around 1% of patients were found to be positive for HIV-I.[17] Because of reduced immunity and increased disease burden, Tuberculosis becomes one of the most common opportunistic infection in HIV positive patients in India.

According to RNTCP guidelines, treatment outcome is measured in terms of cure rate, defaulter rate, failure rate and death rate. In the present study it was observed that out of 663 tuberculosis patients, 37.85% were cured and 43.43% were treatment completed. It reflects the success rate of treatment amongst PTB and EPTB, was 81.28% (cured i.e. 37.85% + treatment completed i.e. 43.43%). S.K. Srivastava conducted a pilot project to evaluate Revised National Tuberculosis Control Program in Luckhnow, observed the treatment success Rate of 82.88%.[18] In this study, over all lost to follow up (defaulters) rate was 5.88%. Dandona Rakhi observed that among new smear positive patients treatment defaulters were 6.8%.[19] V. Chandrasekaran conducted a study in Tiruvallur district Tamilnadu, to study the default and treatment failure among new sputum smear positive patients treated with DOTS. He observed that overall lost to follow up (defaulters) rate in new smear positive patients was 15%.[20] According to RNTCP guidelines overall defaulter rate must not be more than 5% and action is warranted if it is more than 10% among new smear positive cases. Findings in this study suggest that overall defaulter rate was slightly higher than expected. So there is need to strengthen the mechanism for defaulter retrieval by increasing man power, training and

adequate supervision. Overall death rate found in the present study was 8.29%. Many patients died in spite of initiation of treatment because of the reasons like septic shock, respiratory failure, massive haemoptysis with septicaemia and respiratory distress. R Subramani in Tamil Nadu observed 7% death among tuberculosis 1651 patients.[21] In the present study, overall treatment failure rate was found to be 4.52%.

Limitations of the Study

There are few limitations to our study. The main limitation to this study was that, it was a single District Tuberculosis Center based study. Hence, metacentric and community based studies are needed to generalize the results in general population. The other limitation was that the reasons for noncompliance could not be assessed as the Tuberculosis patients were not followed by home visits.

What study adds to existing knowledge?

The present study helps to identify the current trend of compliance of tuberculosis treatment in the region under this District Tuberculosis Center. It also helps to identify the different success rates of DOTS, and thus it will help to formulate preventive strategies which will majorly target to improve the success rates further.

Conclusion

As the maximum cases were from the age group of 25-45 years, there is high burden of Tuberculosis on economically most productive age group. Patients compliance is affected by various factors and hence the health education on tuberculosis and its treatment at community level is most crucial. The orientation and Interaction activities should be carried out involving health workers and volunteers together with tuberculosis patients and community people to minimize the social stigma and help TB patients to get support in completing the treatment.

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