

TO ASSESS THE RESPONSE AND OUTCOME OF THE TB PATIENTS REGISTERED AT DTC REWA OF CENTRAL INDIA

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Abstract

Background-Tuberculosis is a highly infectious disease caused by Mycobacterium tuberculosis. The disease primarily affects lungs so it known as Pulmonary TB and other tissues of the body which is known as Extra-pulmonary TB. The vast majority of TB deaths are in the developing world left untreated, Tuberculosis is treatable with a course of antibiotics. The most successful strategy to treat TB patients is DOTS.

Material and Method: This is a Prospective Longitudinal study conducted among the patients attending DOTS center of DTC located at S.G.M.H. campus Rewa for the Treatment provided under of a definitive time period (as per RNTCP, last quarter of 2014) from 1st Oct to 31st Dec 2014.

Aim & Objective: 1. To observe the sputum conversion rate of study population. 2. To find out the outcome of treatment.

Result: 69.92%were pulmonary tuberculosis and 30.07% was Extra-pulmonary tuberculosis and sputum conversion rate of Pulmonary TB cases at the end of IP in new sputum smear positive cases was 96.66% but at the end of 5 month it was 100%. In retreatment cases Sputum Conversion rate at the end of IP was 89.28% and at the end of 5 month 92.85%.and overall treatment success rate were 90.97%.

Conclusion: At the end of treatment as per DOTS schedules sputum smear examination is mandatory to know the exact treatment cure rate.

Key words: Pulmonary, Extra-Pulmonary, Sputum Conversion, cured, Treatment completed, Defaulter etc.

Introduction

Tuberculosis is a specific infectious disease caused by Mycobacterium tuberculosis. The disease primarily affects lungs and causes Pulmonary TB (PTB).It can also affect intestine, meninges, bones and joints, lymph glands, skin and other tissues of the body which is known as Extra-pulmonary TB. It is transmitted from person to person via droplets from the throat and Lungs of people with the active respiratory TB disease. TB is also called Koch's disease, after the scientist Koch. The bacillus causing TB, Mycobacterium tuberculosis, was identified and described on 24 March 1882 by Robert Koch⁽¹⁾.

The vast majority of TB deaths are in the developing world. Left untreated, each person with active TB disease will infect on average between 10 and 15 people every year and this continues the TB transmission. Overall, one-third of the world's population is currently infected with the TB bacillus. Tuberculosis is treatable with a course of

antibiotics. The most successful strategy to treat TB patients is DOTS. The DOTS (Directly Observed Treatment Short course) strategy of tuberculosis treatment recommended by WHO was based on clinical trials done in the 1970s by Tuberculosis Research Centre, Chennai, India⁽²⁾

The target of DOTS programme is successful treatment or cure rate of 85 % of new smear positive cases and detection of 70% of such cases. In DOTS two phase treatment are given during the intensive phase of treatment a health worker or other trained person watches as a patients swallows the drug in the presence .During continuation phase, the patient is issued medicine for one week in a multi-blister combipack, of which the first dose is swallowed by the patient in presence of health worker or trained person. The consumption of medicine in the continuation phase is also checked by return of empty multi-blister combipack , when the patient come to collect medicine for the next week. The drug are provided in

patient wise boxes with sufficient shelf-life, boxes are colour coded red colour box for category one and blue colour box for category two patient. In the programme alternate day treatment is given.

The outcome of DOTS is measured in many terms like.

Treatment complete- Initially sputum smear-positive patient who has completed treatment with negative smears at end of the intensive phase/two months in the continuation phase, but none at the end of the treatment is declared as treatment completed. Or Initially sputum smear negative patient who has received full course of treatment and has not become smear-positive at the end of the treatment or Extra pulmonary TB patient who has received full course of treatment and has not become smear-positive during or at the end of treatment. **Cured** Initially sputum smear-positive patient who has completed treatment and had negative sputum smears on two occasions, one of which was at the end of the treatment. **Relapse** a TB patient who was declared cured or treatment completed by a physician and who reports back to the health facility and is now found to be sputum smear-positive. **Treatment after default:** A patient, who has received treatment for TB for a month or more from any source and returns for treatment after having defaulted i.e., not taken anti-TB drugs consecutively for two months or more and found to be smear-positive. **Treatment failure:** Any TB patient who is smear-positive at 5 months or more after initiation of treatment. **Transferred in:** A TB patient who has been received for treatment in a Tuberculosis Unit, after starting treatment in another TB unit where s/he has been registered. **Transferred out** A patient who has been transferred to another TU and whose treatment outcome still not available. **Chronic** A patient who remains smear-positive after completing regimen for previously treated but not initiated on MDR-TB treatment. **Others** A patient who does not fit into the any of the types mentioned above. The reasons for labeling a patient under this type must be specified in the Treatment card and TB Register⁽³⁾. Although all the definitions have been revised and applicable since 1st of January 2015.

Tuberculosis is curable disease with a course of antibiotics with DOTS strategy. By keeping this entire thing in mind the present study was conducted at DTC cum DOTS center in Rewa M.P. central India, by considering the objective that to assess the type of patient registered at DTC Rewa response of the patient to the drug and finally the outcome of treatment at the end of course.

Methodology

Study Area: This study was conducted in DTC of Rewa & Department Of Community Medicine, Shyam Shah Medical College, Rewa, M.P. **Study Design:** This is a Prospective Longitudinal study conducted among the patients

attending DOTS center of DTC located at S.G.M.H. campus Rewa for the Treatment provided under of a definitive time period (as per RNTCP, last quarter of 2014) from 1st Oct to 31st Dec 2014. **Study Population:** Only newly registered patients during the last quarter of 2014 a total of 137 patient, out of 137 patients, 4 were MDR patients, so these patients were excluded from the study population because treatment out-come of these MDR patients was not supposed to be completed till the completion of the present study. **Sampling Method:** All newly registered Patients during a particular time period at DOTS center were selected irrespective adopting of any particular sampling method or variables like age, sex, place and Socio economic status etc in the present study. **Data Entry and Analysis:** All the data was collected on pretested questionnaires, on the date of registration. The patients' clinical progress such as "sputum conversion from smear positive to smear negative" are documented in subsequent visits, The collected data were scrutinized for completeness and consistency collected data was analyzed by using MS excel, instat Graph pad and Epi cal info 2000 were used to apply appropriate statistical tests.

Results

In the present study, [Table 1](#) we distributed the Patient distribution according to Type of TB registered in DTC ,Rewa central India in last quarter for treatment .

As table show that 93 patients (69.92%) were pulmonary tuberculosis and 40 (30.07%) was Extra-pulmonary tuberculosis. In pulmonary cases 30(32.25%) were New sputum smear positive and 35 (37.63%) were New sputum smear negative, and 28(30.01%) were retreatment patients. In extra-pulmonary tuberculosis 31(77.5%) were new cases and 9(22.5%) were retreatment cases. In males 60.71 % were pulmonary tuberculosis in females 85.71% were pulmonary tuberculosis This sex-wise distribution of different type of patients was found to be statistically significant (p value=0.0046).

Table I: Patient distribution according to Type of TB

S.N.	Type of Patients	Males (84)	Females(49)	Total (133)
1	Pulmonary	51(60.71%)	42(85.71%)	93(69.92%)
	New sputum Smear Positive	17(33.33%)	13(30.95%)	30(32.25%)
	Retreatment	18(35.29%)	10(23.80%)	28(30.01%)
	New Sputum Smear Negative	16(31.37%)	19(45.23%)	35(37.63%)
2	Extra-Pulmonary	33(39.28%)	7(14.28%)	40(30.07%)
	New cases	25(75.75%)	6(85.71%)	31(77.5%)
	Retreatment cases	8(24.24%)	1(14.28%)	9(22.5%)

Chi square=8.047, d.f.=1, p value=0.0046

In Table-II we observe the response the registered patient to the treatment, so we distribute the patient according to Sputum Conversation status after IP Completion, extension of IP, At the end of two month of continuation phase. Sputum smear examination was done in all pulmonary cases. In the present study shown that the sputum

conversion rate of Pulmonary TB cases at the end of IP in new sputum smear positive cases was 96.66% but at the end of 5 month it was 100%. In retreatment cases Sputum Conversion rate at the end of IP was 89.28% and at the end of 5 month 92.85%. In New sputum smears Negative cases sputum conversion rate at the end of IP was 100% and it was maintained at the end of 5 month even. So in total 93 pulmonary TB cases Sputum Conversion rate at the end of IP was 95.69%, at the end of 5 month was 97.84%.

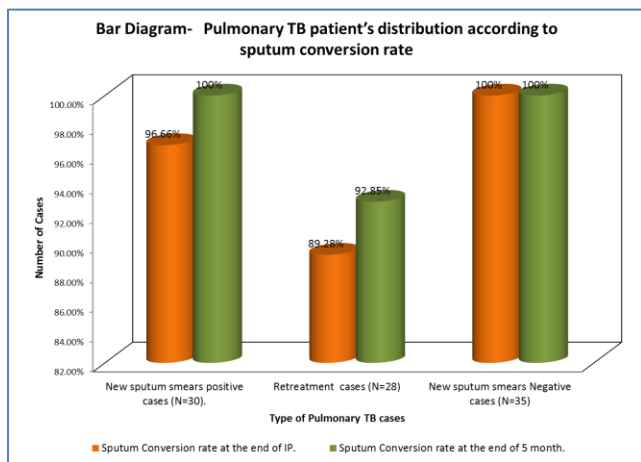
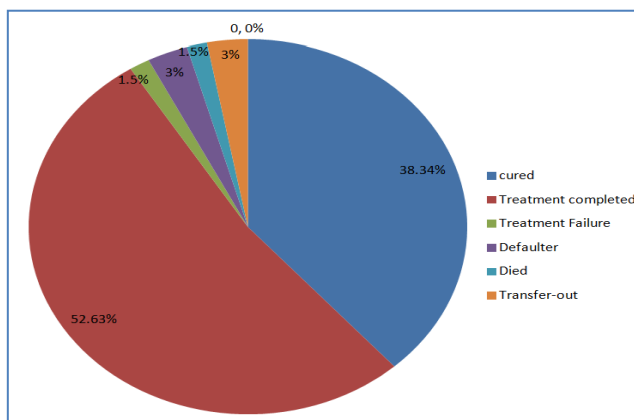


Table-II

A. Patients distribution according to Sputum Conversation status after IP Completion				
S.N.	Type of patients(93)	Sputum smear Conversation	No. of Patients (93)	Percentage (%)
1	New sputum smear positive (30)	Negative	29	96.66
		Positive	01	3.33
2	Retreatment cases (28)	Negative	25	89.28
		Positive	3	10.71
3	New sputum smear Negative (35)	Negative	35	100
		Positive	00	00
B. Patients distribution according to result after extension of IP-				
S.N.	Type of patients(93)	Sputum smear Conversation	No. of Patients (93)	Percentage (%)
1	New sputum smear positive (30)	Negative	29	96.66
		Positive	01	3.33
2	Retreatment cases (28)	Negative	25	89.28
		Positive	3	10.71
3	New sputum smear Negative (35)	Negative	35	100
		Positive	00	00
Patients distribution according to result after two month of CP-				
S.N	Type of patients	Result after two month of CP	No. of Patients (93)	Percentage (%)
1.	New sputum smear positive (30)	Negative	30	100
		Positive	00	00
2.	Retreatment cases (28)	Negative	26	92.85
		Positive	02	7.14
3	New sputum smear Negative (35)	Negative	35	100
		Positive	00	00
D. Pulmonary TB patient's distribution according to sputum conversion rate -				
S.N.	Type of Pulmonary TB cases.	Sputum Conversion rate at the end of IP.	Sputum Conversion rate at the end of 5 month.	
1.	New sputum smears positive cases (N=30).	96.66% (29/30)	30/30=100%	
2.	Retreatment cases (N=28)	25/28=89.28%	26/28=92.85%	
3.	New sputum smears Negative cases (N=35)	35/35=100%	35/35=100%	
	Total=93	89/93=95.69%	91/93=97.84%	

As shown in the pie chart we Distribute the Patients According to Treatment Outcome Out of 133 patients 51(38.34%) patients were cured, 70 (52.63%) were

completed their treatment, so overall treatment success rate were 90.97%.



Discussion

The present study was undertaken at DTC cum DOTS Centre of Rewa District, Madhya Pradesh. Period of study was selected for One Year two months i.e. 1st SEP 2014 to 31st OCT 2015. Pilot testing of the study proforma was done in the month of September. a total of 133 patients included in the present study which were newly registered in the last quarter of 2014 and were receiving drugs at the selected DTC cum DOT Center. After analyzing data, the discussion of the present study is discussed as per following heads

Out of 133 patients 93 (69.92%) were Pulmonary tuberculosis and 40 (30.07%) were Extra-pulmonary tuberculosis. In pulmonary cases 30 (32.25%) were New sputum smear positive and 35 (37.63%) were New sputum smear negative, and 28 (30.01%) were retreatment patients. In extra-pulmonary tuberculosis 31 (77.5%) were new cases and 9 (22.5%) were retreatment cases.

Similarly Maria Nelliyanil et al⁽⁴⁾ (2012) carried out a study and was also found that in the study, 56.5% had pulmonary TB and 43.5 % had extra-pulmonary. The proportion of extra-pulmonary cases observed in the present study is similar to that observed in a retrospective analysis of pediatric TB cases carried out at the LRS institute of TB and Respiratory Diseases, New Delhi by Arora V K et al⁽⁵⁾ (2008) which reported that 47% of the cases were extra-pulmonary TB. While in Kabra et al⁽⁶⁾ (2004) study of the total 459 patients, 70.3% patients were in Category I, 2.6% were in Category II and 26.1% in Category III. This difference may be explained by the fact that their study was hospital-based. However, Now Category III has been merged into Category I or called as the new case regimen when the study was done.

Similarly Marsthi et al⁽⁷⁾ (2006) founded 86.36% cases were suffered from pulmonary TB and 13.64% had extra-pulmonary type of tuberculosis.

Same as **Geeta Pardeshi et al⁽⁸⁾ (2007)** conducted a study in elderly patients in at District Tuberculosis center, Yavatmal and found the distribution of TB pattern in patient that New smear positive was 32.7% ,New smear negative was 47.14%, New extra-pulmonary was 5.72% and Retreatment cases was 14.44% ,these finding also support present study findings. **Sukamal Bisoi et al⁽⁹⁾ (2007)** was found in their study that among 286 patients, total new cases were 224 (78.3%) and 192 (67.1%) were new pulmonary cases. Overall 2.1% were relapse, 1.0% failure, 3.8% treatment after default and 14.7% were of other category. Out of the total 286 cases, pulmonary cases were 248 (86.7%) and extra-pulmonary 38 (13.3%). Among the total 248 pulmonary tuberculosis cases, 113 (45.6%) were sputum smear-positive and among 192 new pulmonary tuberculosis cases, 93 were sputum smear-positive (48.4%).Out of total 286 patients, 103 (36%) were given Cat I regimen, 63 (22%) Cat II regimen and 120 (42%) Cat III regimen. Among 103 Cat I cases, 93 (90.3%) were sputum smear-positive and 10 (9.7%) Were seriously-ill smear-negative or extra-pulmonary cases. These all studies also support the distribution of findings of the present study.

Sputum Conversion: In the present study the sputum conversion rate after IP completion for new smear positive to smear negative status was 96.66%, and retreatment cases it was 89.28% , who were smear positive at the time of enrollment. Thus overall sputum conversion rate of all pulmonary cases at the completion of intensive phase was 94.02%. As per the guidelines of **RNTCP^(10,11)** the sputum conversion rate at the end of intensive phase should be >85% for new sputum positive patients. So we can say that RNTCP programme is running successfully according to guidelines of RNTCP.

out of these four patient extension of IP one month, 2 become sputum smear negative one of category-I and one of category-II, and 2 remain sputum smear positive of category-II. In all patient after IP completion CP was started , Overall sputum conversion rate at the end of 5 months of Pulmonary tuberculosis patient was 97.84 % (91 out 93) and only 2.15% (2 out of 93) were remain sputum smear positive result at the end of 5 months hence these 2 patients were tested for DST and declared ad MDR cases.

Similarly a study conducted by **Sukamal Bisoi et al⁽⁹⁾(2007)** they found that sputum conversion rate for new sputum-positive TB cases at 2 or 3 months was 74.2%, and among all 113 sputum smear-positive cases it was 76.1%.These finding support the finding of present study.Similarly **Arora et al⁽¹²⁾(2003)** found in their study in New Delhi also reported 91% sputum conversion rate for new smear positive patients. Similarly **Srivastava et al⁽¹³⁾ (2000)** found in their study in Lucknow, 92.9% sputum conversion rate

for new smear positive patients, and 81.9% for retreatment cases, who were smear positive at the time of enrollment .All these study was support the finding of present study.In contrast to our observation **Kumaresan et al⁽¹⁴⁾(1998)** found in their study in Bangladesh 85% sputum conversion rate of new sputum positive patients. **Bhat et al⁽¹⁵⁾ (1998)** in their study on RNTCP, An urban experience in Delhi found that the average Sputum Conversion Rate(SCR) at 3 month for new sputum positive patients was 81% and for retreatment cases that were sputum positive at the time of enrollment was 60%.And **Simmi Tiwari et al⁽¹⁶⁾ (2012)** also found that sputum conversion rate after two months of IP showed statistically significant difference between the two cohorts (High Prevalence(HP) Cohort-57.9% and Low Prevalence (LP) Cohort-71.6%; p value 0.008). The cumulative SCR after extended IP was also significantly different between the two cohorts (HP Cohort- 85.2% and LP Cohort-92.3%; p value 0.03).Similarly **S.L.Chadha et al⁽¹⁷⁾ (2000)** found that the sputum conversion rate was 92.6% and 76.9% in category I and category-II patients at the end of intensive phase.

Treatment outcome: In the present study Out of 133 patients 38.34% patients were cured, 52.63% were completed their treatment, 1.50% got failure of RNTCP treatment, 3% were undergone defaulter, 1.50% were died during treatment and 3% were gone transferred out from DTC cum DOTS center to another TU and 1.50% were switched over to MDR treatment during the course of treatment.

Similarly a study conducted by **K. Venugopal et al⁽¹⁸⁾ (2008)** found that A total of 32 cases registered for DOTS regimen were out of whom 29 completed the treatment and all were asymptomatic at the end of treatment (85%). **Maria Nelliyanil et al⁽⁴⁾(2012)** found that in the study, 56.5% had pulmonary TB and 43.5 % had extra-pulmonary TB. 94.7% of the patients completed treatment. **Varthi Mahendra K et al⁽¹⁹⁾(2014)** found that the findings of treatment outcome of TB patients, Cured 104 (23.53%), treatment completed 289 (65.38%), defaulters 20 (4.52%), treatment failures 1 (0.23%), deaths 25 (5.66%) and transferred out 3 (0.68%),these all findings also support the findings of the present study.

Conclusion; Up on the basis of the findings of the present study the ratio of pulmonary TB cases and extra pulmonary TB cases of the present study were not matched to the set guidelines of RNTCP because in the present study only a single Quarter i.e. In the present study although treatment compliance and treatment success rate is also found to be higher but even conversion of fewer patients to defaulters and treatment failure is warning towards how to prevent the emergence of even a single case of MDR/XDR TB. At the end of treatment as per DOTS schedules sputum smear examination is

mandatory to know the exact treatment cure rate but still as per findings of the present study it has been observed that there is lack of follow up for sputum smear examination of patients at the end of completion of treatment. Such attempts regarding sputum smear examination at the end of treatment can stop further spread of MDR/XDR and can also help to detect treatment failure

Declarations:

Ethical approval and consent to participate:

The research proposal was approved by Ethics Review Committee of the Shyha Shah Medical Collage Rewa, informed consent was obtained from all the participant.

Consent to publish:

Administrative authorities consented the collection and publication of data. All authors read the manuscripts and agreed to publish.

Authors' contributions

PA and SG conceptualized the study. AN and AJ and SP involved in the data collection process. AN and SS assisted the data analysis and manuscript preparation to PA. All authors read and approved the final manuscript

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