

## AN OVERVIEW OF ANTI-TUBERCULOSIS TREATMENT (ATT) IN CAT I NEWLY DIAGNOSED CASES OF TUBERCULOSIS IN RNTCP

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### ABSTRACT

#### BACKGROUND

Tuberculosis (TB) remains a global public health problem and a major cause of death from a single infectious agent among adults in India and other developing countries. The aim of this study is to characterise effectiveness and outcome of antituberculosis treatment among newly diagnosed patients in RNTCP.

#### MATERIALS AND METHODS

This is a retrospective descriptive study of a newly diagnosed TB patients of all age groups attending OPD of various departments of LN Medical College and JK Hospital, Bhopal, M. P. (India) between a period of January 2012 and September 2015.

#### RESULTS

A total of 360 patients were found eligible for this study, who were diagnosed and received ATT under DOTS in RNTCP. In different age groups percentage of patients observed were 14.72%, 65.28% and 20.00% in 0 - 14 years, 15 - 45 years and above 45 years respectively.

#### CONCLUSION

Maximum patients 65.28% (235) were registered in the age group of 15 – 45 years. Overall, treatment outcome were observed as follows- 86.39% treatment successful, 6.11% defaulted, 2.78% failed and 4.17% died. Higher percentage of treatment successful (98.11%) was observed in the age group of 0 - 14 years, whereas higher percentage of both defaulter (12.50%) and mortality (15.28%) with lower treatment successful rate (68.06%) were observed in the age group of above 45 years. Higher percentage of defaulter, failure and mortality were observed in males and PTB patients in comparison to females and EPTB. Overall, significant weight gain (92.60%) with treatment being successful (86.39%) were observed in this study.

#### KEYWORDS

ATT, Newly Diagnosed TB, DOTS, RNTCP.

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#### BACKGROUND

Tuberculosis (TB) remains a global public health problem and a major cause of death from a single infectious agent among adults in India and other developing countries.<sup>[1,2,3,4]</sup> The problem is further compounded by the emergence of HIV, DM and DR (Drug Resistance) TB. According to WHO 6.1 million TB cases were reported in 2013, out of which 5.7 million cases were newly diagnosed and another 0.4 million were already on treatment.<sup>[5]</sup>

The burden of TB in India is the highest accounting for approximately one-fifth (21%) of the global incidence.<sup>[6]</sup>

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Every year 1.8 million new cases occur in India, out of which 0.8 million are infectious.<sup>[7]</sup> As per Revised National Tuberculosis Control Programme (RNTCP) 2011 in Madhya Pradesh, there were 90,764 cases registered for TB.<sup>[8]</sup>

In India, National Tuberculosis Control Programme (NTP) was launched in 1962. NTP was integrated and implemented through the general public health services.<sup>[9]</sup> NTP could not achieve the objective because of low priority, managerial weakness, over dependence on x-ray chest for diagnosis and inadequate funding. In order to overcome the shortcomings in the NTP, WHO and Government of India revised the programme jointly in 1992. WHO declared TB, a global health emergency in April 1993.<sup>[10]</sup> The Revised National Tuberculosis Programme (RNTCP) has been implemented in 1993, guided by WHO and supported by world bank.<sup>[11]</sup>

A five-point strategy known as Directly Observed Treatment Short course (DOTS) was launched in India in a phased manner under RNTCP in 1997 with objective of cure rate not less than 85% of infectious TB cases and at least 70% detection of new cases through quality sputum microscopy.<sup>[12,13]</sup>

With this background, we conducted this retrospective study at LN Medical College and JK Hospital, Bhopal, M. P. (India).

## MATERIALS AND METHODS

### Aim

The aim of this study is to characterise effectiveness and outcome of antituberculosis treatment among newly diagnosed patients in RNTCP.

### Study Design

This is retrospective descriptive study of newly diagnosed TB patients of all age groups.

### Study Areas

The study was conducted in the LN Medical College and JK Hospital, Bhopal (MP), a tertiary care centre, so patients from urban, nearby villages and adjoining districts who were referred for diagnosis and treatment of tuberculosis.

### Study Period

Data for this study has been obtained between a period of January 2012 and September 2015.

### Study Population

The population includes all patients attending various OPD of this institute who suspected of TB infection during the study period. This study includes a total of 360 patients diagnosed microbiologically, pathologically and radiologically as TB in LN Medical College and JK Hospital, Bhopal (MP).

### Source of Information

For this study data has been obtained from DOTS treatment cards, RNTCP referral register, patient record sheet of hospital and laboratory register.

### Inclusion Criteria

All new tuberculosis patients of any age group registered as per RNTCP guidelines.

### Exclusion Criteria

Patients having comorbid diseases like DR, TB and HIV. The patients were started on standard regimens of anti-tuberculosis drugs as provided by Government of India under DOTS for category I patients. During intensive phase, every dose of anti-tuberculosis drugs were taken in front of health worker or DOTS provider followed by continuation phase during which first dose of weekly ATT pack were given under direct observation of health worker or DOTS provider and remaining two doses of weekly pack has been taken by patient themselves at their home.

Data were scrutinised and cross checked twice in order to ensure accuracy and corrected for discrepancy or any missing information.

### Definitions

#### Cured

Initially, sputum smear positive patients who have completed treatment and have negative sputum smear on at least two occasions, out of which one at completion of treatment.

#### Treatment Completed

Sputum negative patients who had received full course of ATT has not become smear positive during or at the end of the treatment.

#### Defaulted

A patient who had not taken ATT for one month or more consecutively after one month of starting the treatment.

#### Failure

Smear positive cases who remain smear positive at 5 months or more after starting the treatment. Also includes patients who was initially smear negative, but become positive during treatment.

#### Died

Patient who died during treatment regardless of cause of death.

#### Transfer Out

A patient who has been transferred to another TB unit/district and for whom the treatment results (outcome) is not known.

#### Treatment Successful

The sum of 'cured' and 'treatment completed' patients.

## RESULTS

A total of 360 patients were found eligible for this study, who were diagnosed as new cases of tuberculosis and started CAT I ATT under DOTS in RNTCP. Out of total patients, 55.00% (198) were male and 45.00% (162) were female. Patients registered of pulmonary tuberculosis and EPTB were 65.56% (236) and 34.44% (124). Maximum patients 65.28% (235) were registered in the age group of 15 - 45 years and minimum 14.72% (53) were found in the age group of 0 - 14 years. Maximum 58.08% (115) and 74.07% (120) of total male and female patients were also registered in the same age group of 15 - 45 years.

Overall treatment outcome was observed as follows- 86.39% (311) treatment successful, 27.78% (100) cured, 58.61% (211) treatment completed, 6.11% (22) defaulted, 2.78% (10) failed, 0.00% (0) relapsed, 4.17% (15) died and 0.56% (2) transferred out. Successful treatment in patients were observed as follows- 80.81% (160), 93.21% (151), 82.20% (194) and 94.35% (117) respectively in males, females, pulmonary TB and EPTB patients. Higher percentage of defaulter, failure and mortality were 8.08% (16), 3.03% (6) and 7.07% (14) observed in males as compared to female patients. Higher percentage of defaulter, failure and mortality were 8.05% (19), 3.81% (9) and 5.08% (12) observed in pulmonary TB patients as compared to EPTB patients. Out of total 236 treated patients of pulmonary tuberculosis, treatment outcomes were observed as follows- 82.20% (194) treatment successful, 42.37% (100) cured, 39.83% (94) treatment completed, 8.05% (19) defaulted, 3.81% (9) failed, 0.00% (0) relapsed, 5.08% (12) died and 0.85% (2) transferred out.

Out of total 130 sputum smear positive PTB patients, cure rate, defaulted, failed and died were observed as 76.92% (100), 10.00% (13), 6.92% (9) and 5.38% (7) respectively.

In sputum smear positive patients, higher percentage of treatment successful 79.60% (78) was observed in the age group below 45 years, while higher rate of default (18.75%) and mortality (12.50%) were observed in the age group of above 45 years.

In this study overall weight gain, weight constant and weight loss observed were 92.60% (288), 3.86% (12) and 3.54% (11) patients.

Higher percentage of treatment successful was 98.11% (52) observed in the age group of 0 - 14 years, while higher percentage of both defaulter (12.50%) and mortality (15.28%) were observed in the age group of above 45 years as compared to other age groups.

Group	0-14 yrs. 14.72% (53)	15-45 yrs. 65.28% (235)	Above 45 yrs. 20.00% (72)	Total (360)
Male	16.67% (33)	58.08% (115)	25.25% (50)	55.00% (198)
Female	12.35% (20)	74.07% (120)	13.58% (22)	45.00% (162)
EPTB	16.13% (20)	68.55% (85)	15.32% (19)	34.44% (124)
Pulmonary TB	13.98% (33)	63.56% (150)	22.46% (53)	65.56% (236)
Sputum positive TB	0.77% (1)	73.08% (95)	26.15% (34)	36.11% (130)
Sputum negative TB	30.19% (32)	51.89% (55)	17.92% (19)	29.44% (106)
Weight gain	17.71% (51)	66.32% (191)	15.97% (46)	92.60% (288/311)
Weight constant	8.33% (1)	83.34% (10)	8.33% (1)	3.86% (12/311)
Weight loss	9.09% (1)	72.73% (8)	18.18% (2)	3.54% (11/311)

**Table 1. Age Wise distribution of Patients in different Group of Sex, Site Involvement, Sputum Status and Weight Variation**

	Treatment Successful 86.39% (311)	Cured 27.78% (100)	Treatment Completed 58.61% (211)	Default 6.11% (22)	Failure 2.78% (10)	Relapsed 0.0% (0)	Expired 4.17% (15)	Transfer Out 0.56% (2)	Total (360)
0-14 yrs.	98.11% (52)	1.89% (1)	96.23% (51)	1.89% (1)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	14.72% (53)
15-45 yrs.	89.36% (210)	32.77% (77)	56.60% (133)	5.11% (12)	3.83% (9)	0.0% (0)	1.70% (4)	0.0% (0)	65.28% (235)
Above 45 yrs.	68.06% (49)	30.56% (22)	37.50% (27)	12.50% (9)	1.39% (1)	0.0% (0)	15.28% (11)	2.78% (2)	20.00% (72)
Male	80.81% (160)	27.27% (54)	53.54% (106)	8.08% (16)	3.03% (6)	0.0% (0)	7.07% (14)	1.01% (2)	55.00% (198)
Female	93.21% (151)	28.40% (46)	64.81% (105)	3.70% (6)	2.47% (4)	0.0% (0)	0.61% (1)	0.0% (0)	45.00% (162)
EPTB	94.35% (117)	0.0% (0)	94.35% (117)	2.42% (3)	0.81% (1)	0.0% (0)	2.42% (3)	0.0% (0)	34.44% (124)
PTB	82.20% (194)	42.37% (100)	39.83% (94)	8.05% (19)	3.81% (9)	0.0% (0)	5.08% (12)	0.85% (2)	65.56% (236)
Sputum Neg. PTB	88.68% (94)	0.0% (0)	88.68% (94)	5.66% (6)	0.0% (0)	0.0% (0)	4.72% (5)	0.94% (1)	29.44% (106)
Sputum Pos. PTB	76.92% (100)	76.92% (100)	0.0% (0)	10.00% (13)	6.92% (9)	0.0% (0)	5.38% (7)	0.77% (1)	36.11% (130)
Sputum Positive < 45 yrs.	79.60% (78)	79.60% (78)	0.0% (0)	7.14% (7)	9.18% (9)	0.0% (0)	3.06% (3)	1.02% (1)	27.22% (98)
Sputum Positive > 45 yrs.	68.75% (22)	68.75% (22)	0.0% (0)	18.75% (6)	0.0% (0)	0.0% (0)	12.50% (4)	0.0% (0)	8.89% (32)

**Table 2. Outcome in different Age Group, Sex, Site and Sputum Status**

**DISCUSSION**

This present study was done to categorise the efficacy and treatment outcome of ATT drugs in tuberculosis patients put on DOTS in RNTCP. In this study, higher proportion of males 55.00% were affected by TB as compared to females. Higher proportion of males were also observed in study at Nagpur (68.99%).<sup>[14]</sup> In this study 45% female patients were

registered, while 31.01% female patients were registered in study at Nagpur.<sup>[14]</sup>

In this study, maximum patients 65.28% were registered in the age group of 15 - 45 years, which reflects that tuberculosis disease is more commonly affecting reproductive and working population in both males and females which can affect the scenario of economy of any country.

In this study successful treatment rate observed were 86.39% which coincides with 96.13%, 78.10% and 77.14% found in different studies at Nagpur, Zenebe Y et al and Aurangabad respectively.<sup>[14,15,16]</sup>

The cure rate was calculated as 27.78% in this study. This data coincide with 35.24%, 45.74%, 47.66% and 13.80% found in different studies at Aurangabad, Nagpur, Delhi and Jemal M et al.<sup>[14,16,17,18]</sup>

Overall treatment completed patients observed in this study were 58.61%, while 50.39%, 41.90% and 51.50% were observed in different studies done at Nagpur, Aurangabad and Jemal M et al.<sup>[14,16,18]</sup>

Overall default rate in this study is 6.11%, which coincides with 5.98%, 2.33%, 19.05% and 3.80% observed in different studies at Delhi, Nagpur, Aurangabad and Jemal M et al.<sup>[14,16,17,18]</sup> The average rate of default in India were 4% among Category I.<sup>[7]</sup> As age advanced, percentage of defaulters increased in this study from 1.89% in 0 - 14 years age group to 12.50% in the age group above 45 years. The percentage of defaulters was high among males, 8.08%. Possible causes of default may be feeling of wellbeing in early phase of treatment, side effect of drugs, facing difficulty to attend DOTS centre, financial loss on day of medication due to absence from work, social stigma to attend DOTS centre, rude behaviour of some DOTS provider, less faith towards government health organisations and migration of labourers. Continuing education and motivation can reduce defaults at all stage of treatment. To reduce default rate and increase case detection, it is suggested that government should also provide ATT under DOTS by mobile van with in-built facilities of sputum smear examination, portable chest x-ray machine, trained staff and medicines to treat side effect of ATT.

Dense population, little health awareness, increasing trend of nuclear family, unhealthy lifestyle, increasing stress in job, lesser pre-employment health checkup of maids/drivers and affecting young adults are major risk factors for delayed diagnosis, delay in starting of treatment and increasing burden of Category I TB and later Category II/ DRTB which can affect individual family condition and economy of country as well.

Total sputum smear positive patients observed in this study was 36.11% while 45.42%, 47.62%, 66.67%, 26.80% and 9.8% were observed in different studies done at Delhi, Aurangabad, Nagpur, Jemal M et al and Zenebe Y et al.<sup>[14,15,16,17,18]</sup>

Total sputum smear negative pulmonary TB patients observed in this study was 29.44%, while 23.25% and 31.80% were observed in different studies done at Nagpur and Zenebe Y et al.<sup>[14,15]</sup>

All family members, close contact of specially sputum positive patients should be strictly evaluated for early detection of tuberculosis and early starting of ATT.

In present study overall failure rate was observed in 2.78% while 1.12%, 0.78% and 0.7% were observed in study of Delhi, Nagpur and Jemal M et al respectively.<sup>[14,17,18]</sup> However, it was comparable with average rate of India, i.e. 1.5% Category I.<sup>[6]</sup>

As per RNTCP data the prevalence of EPTB in non-HIV patients was 15 - 20%, but in this study it was 34.44% which is more than the RNTCP statistics. This increase in prevalence of EPTB is due to easy availability of advanced diagnostic

facilities at low cost in medical college setup<sup>[19]</sup> and ours is a tertiary care referral centre.

Overall death rate in this study observed was 4.17% while 2.86%, 2.80%, 0.93% and 0.78% found in different studies at Aurangabad, Jemal M et al, Delhi and Nagpur.<sup>[14,16,17,18]</sup>

The treatment successful rate (68.06%) were low, but rate of default (12.50%) and mortality (15.28%) were high among elderly patients age above 45 years. Tuberculosis in elderly age group is most often associated with reactivation of endogenous infection, poor nutritional status, co-morbidities, atypical clinical features, delayed diagnosis and neglected by some family members, so patients seek medical advice in more advanced stage which can lead to higher mortality.

Overall weight gain, weight constant and weight loss were observed in 92.60%, 3.86% and 3.54% patients in this study, which coincides with 91.10%, 5.6% and 3.30% in Chennai study.

This study shows that anti-tuberculosis treatment under DOTS in RNTCP is running successfully in the study region with good success rate and low default rates.

This study had several limitations; the main limitation is that being a retrospective and tertiary care level hospital-based study, finding cannot be generalised/applied to the whole community, but it gives important information regarding tuberculosis management under DOTS in Bhopal, M.P. (India).

## CONCLUSION

This study showed that tuberculosis disease is now more affecting young adult population, which is a very worrisome fact. In different age groups percentage of patients observed were 14.72%, 65.28% and 20.00% in 0 - 14 years, 15 - 45 years and above 45 years respectively.

Overall treatment outcome was observed as follows- 86.39% treatment successful, 6.11% defaulted, 2.78% failed and 4.17% died.

Higher percentage of successful treatment was 98.11% observed in the age group of 0 - 14 years as compared to other age group. Higher percentage of both defaulter (12.50%) and mortality (15.28%) with lower treatment successful rate (68.06%) were observed in the patient's age group of above 45 years as compared to other age groups.

Overall, significant weight gain (92.60%) with successful treatment (86.39%) were observed in this study.

## List of Abbreviations-

EPTB	- Extra-Pulmonary Tuberculosis.
PTB	- Pulmonary Tuberculosis.
ATT	- Anti-Tuberculosis Treatment.
TB	- Tuberculosis.
RNTCP	- Revised National Tuberculosis Control Programme
DOTS	- Directly Observed Treatment Short Course Chemotherapy.
HIV	- Human Immunodeficiency Virus.
DR	- Drug Resistance.
DM	- Diabetes Mellitus.

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