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Original Research Article

# Outcomes in patients of pulmonary tuberculosis treated under RNTCP & follow up after 6 months

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ABSTRACT

**Background:** Tuberculosis (TB) is, one of the top 10 causes of death worldwide and the leading cause of death from a single infectious agent.
**Materials and Methods:** This Prospective study was conducted at Santosh medical college Ghaziabad from $1^{st}$ April 2018 to $30^{th}$ September 2019. All diagnosed PTB patients above 12yrs were taken. Patients with EPTB, HIV positive, MDR TB, XDR TB were excluded from the study. At the end of study treatment outcome was evaluated.
**Results:** Total of 208 patients diagnosed as tuberculosis were enrolled in the study. 6 patients died during course of study, 10 were treatment failure, 4 were lost to follow-up, 3 transferred out & 1 shifted to private treatment. 184 patients completed treatment successfully. Out of 184, only 152 patients were available for interview at 6 months follow up after completion of treatment. 19 could not be traced, 11 patients refused and 2 died. Out of 152, 110 were asymptomatic, 1 relapsed & rest 41 patients were symptomatic. All symptomatic patients were subjected to Chest X-Ray. Fibrosis was seen on CXR of 30 patients, bronchiectasis was seen in 3 patients, 1 patient had destroyed lung, nothing abnormal detected in 7 patients.
**Conclusion:** Even after successful treatment under RNTCP, these patients need to be followed up as many of them relapse or suffer from sequelae of tuberculosis.



## 1. Introduction

Studies of human skeletons show that Tuberculosis has affected humans for thousands of years – but its cause remained unknown until discovery of Mycobacterium tuberculosis by Dr Robert Koch in 1882.[1,2] Tuberculosis (TB) is, one of the top 10 causes of death worldwide and the leading cause of death from a single infectious agent (ranking above HIV/AIDS).[3] An estimated 10 million (range, 9.0– 11.1 million) people fell ill with tuberculosis (TB) in 2018, a number that has been relatively stable in recent years. There were an estimated 1.2 million (range, 1.1–1.3 million) TB deaths among HIV-negative people in 2018.

Eight countries account for two thirds of the global TB burden, with India (27%) leading the count. India accounts for more than one fourth (27%) of the global TB burden i.e. 27 Lakh (2.69 Million) out of 10 million (1crore) new cases annually.[4] Mortality of TB in India is 440,000 which was 31% of the Global TB deaths (1.2 million) provided by WHO for the year 2018.

The National Tuberculosis Control Programme (NTP) of India was initiated in 1962. Following review in 1992, the Revised National Tuberculosis Control Programme (RNTCP), incorporating the components of the internationally recommended Directly Observed Treatment Short-course (DOTS) strategy for the control

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of TB, was developed.In April 1993, the World Health Organization declared Tuberculosis as a global emergency because of the high mortality rates among adults, its association with HIV infection and the emergence of Multi Drug Resistance Tuberculosis (MDR-TB). Previously the objectives of the RNTCP were to achieve at least 85 percent cure rate among the new smear positive cases initiated on treatment, and thereafter a case detection rate of at least 70 percent of such cases. In $12^{th}$ five year plan with a vision of TB free India NSP was announced. The goal of the NSP is to achieve universal access to quality TB diagnosis and treatment for all TB patients in the community. The five objectives of the National Strategic Plan were to achieve 90% notification rate for all cases, to achieve 90% success rate for all new and 85% for retreatment cases, to significantly improve the successful outcomes of treatment of DR -TB cases, to achieve decreased morbidity and mortality of HIV associated TB. to improve outcomes of TB care in the private sector. Over a period of time, there are several landmark achievements including policy and system preparedness for Universal access to TB care including mandatory notification of TB cases, development of Standard for TB Care in India, Comprehensive Real time TB Information Management System – NIKSHAY, use of rapid molecular diagnostics, successful innovations in Private Sector engagement for TB care- Universal Access To TB Care (UATBC). Government of India has committed to end TB by 2025, five years ahead of the global target under Sustainable Development Goals (SDGs). In view of End TB targets, at the start of 2020 the central government has renamed the RNTCP the National Tuberculosis Elimination Program (NTEP).[5] The vision of NTEP is that the people suffering from TB receive the highest standards of care and support from all healthcare providers of their choice (including private sector). However, it needs to be remembered that under NTEP all types of TB cases are diagnosed and treated.

RNTCP has provision of follow-up of cured patients till 2 yrs at 6,12,18 and 24 months after cure which is rarely done and therefore we hardly know what happen to these cases once they are declared as cured and released in community.Very few follow up studies are available. So the purpose of my study is to re-assess treatment outcome of PTB with recently provided better facilities in Ghaziabad.

## 2. Materials and Methods

### *2.1. Type of study*

A prospective study.

### *2.2. Place of study*

Santosh Medical College & Hospital, Ghaziabad, U.P.

### *2.3. Inclusion criteria*

1. Age >= 12 yrs
2. Patients diagnosed pulmonary TB and started treatment under RNTCP (DOTS center) at Santosh hospital, Ghaziabad, during enrollment period.

### *2.4. Exclusion criteria*

1. Patients not willing to be part of study.
2. Patients with EPTB, HIV positive, MDR TB, XDR TB.

### *2.5. Methodology*

The present Prospective study was conducted in department of pulmonary medicine, Santosh medical college and hospital, Ghaziabad with attached DOTS center from $1^{st}$ April 2018 to $30^{th}$ September 2018. All diagnosed PTB patients were taken. Patients were informed about study and consent taken for their participation. Approval from ethical committee of hospital was taken. A detailed history of patient was taken regarding socio-demographic, educational, economic, occupational status & any previous treatment. Patients were followed up regularly and required lab investigations, CXR, & sputum smear examination were performed. After completion of treatment patient were followed till 30 September 2019. At the end of study treatment outcome was evaluated.

### *2.6. Treatment analysis*

The first dose of DOTS was given to the patients in our DOTS center. The patients then were referred to our TU (treatment unit) and treatment was given with the help of RNTCP DOTS provider. ATT in DOTS Regimen is a fixed dose combination of isoniazid 75 mg, rifampicin 150mg, ethambutol 275mg, pyrazinamide 400mg in intensive phase given for 8 weeks (56 days). DOTS continuation phase include fixed drug combination of isoniazid 75mg, rifampicin 150mg, ethambutol 275mg given for 16 weeks (112 days). Number of FDC-tablets given according to weight of patient, 2 tabs for 25-39kg, 3 tabs for 40-54kg, 4 tabs for 55-70 kg, 5 tabs for patients weighing more than 70kg. This weight band got changed since June 2018, according to which 2 tabs for 25-34kg, 3 tabs for 35-49kg, 4 tabs for 50-64kg, 5 tabs for 65-75kg, 6 tabs for patient weighing more than 75kg. ATT started in patients who were sputum positive for AFB or clinically diagnosed as pulmonary tuberculosis on basis of chest x-ray and symptoms. Sputum CBNAAT was sent before ATT irrespective of AFB status to detect rifampicin resistance. Rifampicin resistant patients were treated on lines of MDR-TB if LPA positive, which is not part of present study. Sputum AFB was repeated at end of IP, if still positive than sputum culture was be done to detect MDR-TB. If sputum

AFB converts to negative then we start continuation phase of treatment. Sputum AFB was repeated at end of CP, if negative then stop ATT, treatment is completed. If positive then continue ATT and do LPA, continue ATT till LPA comes negative.

Follow up was done after 6 months of completion of treatment. All available patients were interviewed & examined. Sputum examination & Chest–X-ray was advised if indicated. If they came smear positive and radiologically any chest lesions suggesting pulmonary Koch's was seen then patient were re-evaluated and were managed accordingly.

### 2.7. Statistical analysis

All variables are described by proportions and differences between independent groups were compared using the chi-square test. P<0.05 was considered as statistically significant.

### 2.8. Case definitions

#### 2.8.1. Microbiologically confirmed TB case

Presumptive TB patient with biological specimen positive for acid fast bacilli, or positive for mycobacterium tuberculosis for culture, or positive for tuberculosis through quality assured rapid diagnostic molecular test.

#### 2.8.2. Clinically diagnosed TB case

Presumptive TB patient who is not microbiologically confirmed, but has been diagnosed with active TB by clinician on the basis of x-ray abnormalities, histopathology or clinical signs with a decision to treat patient with a full course of anti TB treatment.

#### 2.8.3. New case

A TB patient who never had treatment for TB or has taken ATT for less than one month.

#### 2.8.4. Previously treated patients

A TB patient who have received ATT for one month or more in past.

#### 2.8.5. Recurrent TB case

A TB patient previously declared as successfully treated (cured/treatment completed) and is subsequently found to be microbiologically confirmed TB case.

#### 2.8.6. Treatment after failure

Patients who have previously been treated for TB and whose treatment failed at the end of their most recent course of treatment.

#### 2.8.7. Treatment after loss to follow-up

A TB patient previously treated for TB for one month or more and was declared loss to follow-up in their most recent course of treatment and subsequently found microbiologically confirmed TB case.

#### 2.8.8. Other previously treated patients

Patients who have previously treated for TB but whose outcome after their most recent course of treatment is unknown or undocumented.

#### 2.8.9. Transferred in

A TB patient who is received for treatment in a tuberculosis unit, after registered for treatment in another TB unit.

### 2.9. Treatment outcomes

#### 2.9.1. Cured

A microbiologically confirmed TB at the beginning of the treatment who was smear- or culture negative on two occasions, one of which was at the end of complete treatment.

#### 2.9.2. Treatment completed

The patients in whom treatment was completed were sputum smear-positive patient who has completed treatment, with negative smears at the end of the intensive phase (IP) but none at the end of treatment or sputum smear-negative TB patient who has received a full course of treatment and has not become smear-positive during or at the end of treatment or extrapulmonary TB patient who has received a full course of treatment and has not become smear-positive during or at the end of treatment.

#### 2.9.3. Treatment success

TB patients either cured or treatment completed, are accounted in the treatment success.

#### 2.9.4. Failure

A TB patient whose biological specimen is positive by smear or culture at the end of the treatment.

#### 2.9.5. Lost to follow-up

TB patient whose treatment was interrupted for one consecutive month or more.

#### 2.9.6. Not evaluated

TB patient for whom no treatment outcome is assigned (Former transfer out).

#### 2.9.7. Treatment regimen changed

Previously, it was called as switched over to MDR treatment.

*2.9.8. Died*

Patient who has died during the course of anti-TB treatment.

*2.9.9. Sputum conversion rate*

Sputum conversion rate was calculated as percentage of the number of sputum smear-positive cases converted to sputum smear-negative at the end of IP divided by total number of sputum smear-positive patients initiated on the treatment.

*2.9.10. Cure rate*

Cure rate was calculated as percentage of total number of patients cured divided by the total number of NSP cases registered for the treatment.

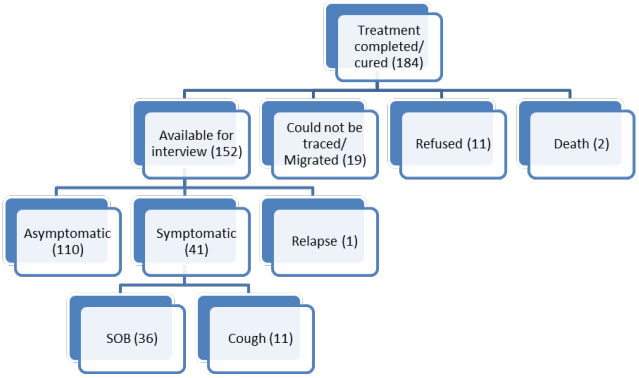


**Fig. 1:** Follow up after 6 months of treatment completion

## 3. Observations and Results

Total of 208 patients diagnosed as tuberculosis were enrolled in the study from the outpatient department of pulmonary medicine at Santosh Hospital, Ghaziabad.

**Table 1:** Outcome at the end of treatment completion

| Outcome | Frequency (n=208) | Percent (%) |
|---|---|---|
| LFU | 4 | 1.9 |
| Transferred out | 3 | 1.44 |
| Treatment failure | 10 | 4.8 |
| Death | 6 | 2.9 |
| Treatment completed / Cured | 184 | 88.5 |
| Shift to private Tt | 1 | 0.48 |

Mean age of patients was 34.2 years. Majority of patients (59.8%) were in 26-40 years age group. 55.9% participants were male while females comprised 44.1% of study population. In present study 6 patients died during course of study, 10 patients were treatment failure, 4 patients were lost to follow-up. Thus total 20 patients were considered as adverse outcome and 184 patients completed treatment successfully. Rest 4 patients (3 transferred out & 1 shifted to private treatment) were not considered for further analysis. Hence total 204 patients were cross analyzed.

Total 41 patients complained of shortness of breath & cough at 6 months follow up after completing treatment. All symptomatic patients were subjected to Chest X-Ray. Fibrosis was seen on CXR of 30 patients, bronchiectasis was seen in 3 patients, 1 patient had destroyed lung, nothing abnormal detected in 7 patients.

## 4. Discussion

In the present study during course of treatment 4 patients (1.9%) were LFU, 3 patient transferred out, 1 patient shifted to private treatment, 6 patients (2.9%) died, treatment failed in 10 patients (4.8%), 184 patients (88.5%) improved and it remained same at end of treatment. In their study Vandana Bhoi et al[6] found that out of 806 patients enrolled, 208 patients (25.8%) were cured, 466 (58.4%) patients completed their treatment, 32 patients(3.8%) were defaulters, 71 patients (8.8%) died, treatment failed in 16 patients(2%), 14 patients(1.7%) were LFU/transferred out. In our study treatment failure was high (4.8%) as compared with this study (2%), which may be due to initial heavy bacillary load. In our study 1.9% patients defaulted which is lower than Vandana Bhoi et al[6](3.8%) & (7.7%) SL Chadha study.[7] Two of our cases defaulted during intensive phase both being daily wage labourers. Other two cases defaulted due to feeling well after completion of intensive phase. Bhoi et al[6] found various reasons for default i.e. effect on daily wages of patients belonging to lower socioeconomic status, lack of awareness & ignorance in illiterate patients, migrants moving to their native place. Lower default rate despite most of the patients in our study belonging to lower socioeconomic class could be due to better awareness & counselling.

In the present study patients were followed up after 6 months of completion of treatment, 2 patients died after treatment completion while 6 patients were already dead during course of treatment so total 8 patients died. All these deaths were due to TB. Our death rate of 2.9% (6/208) is in accordance with RNTCP goal of less than 4% & much lower than many other studies. A study conducted by VD Karanjekar et al[8] noticed 103 patients (82.4%) were alive, 22 patients (17.6%) dead during follow up visit. They found 18 of their patients died due to TB or its sequelae. Aradhana Sharma et al.[9] also found 10.7% (14/130) mortality. Vandana Bhoi[6] noticed 8.8% (71/806) death rate, but HIV contributed in death of a significant number of patients, 27(3.3%). In our study none of the patient had HIV.

In our study male patients had significantly poorer outcomes as 16 out of 20 patients with adverse outcomes were male. Three out of four defaulters & four out of six dead were also males. Karanjekar et al.[8] also found default as well as death rate higher among males. Treatment completion rate was also higher among females although

**Table 2:** Association between adverse out come and various variables

| Variables | | Adverse Out Come | | Total | P-value |
|---|---|---|---|---|---|
| | | Yes | No | | |
| Age | <25 | 4(9.1%) | 40 (90.9%) | 44 (100.0%) | 0.699 |
| | 26-40 | 12 (9.9%) | 110 (90.1%) | 122 (100.0%) | |
| | 40-60 | 2 (7.1%) | 26 (92.9%) | 28 (100.0%) | |
| | >60 | 2 (20.0%) | 8 (80.0%) | 10 (100.0%) | |
| | Total | **20 (9.8%)** | **184 (90.2%)** | **204 (100.0%)** | |
| Sex | Female | 4 (4.4%) | 86 (95.6%) | 90 (44.1%) | **0.022** |
| | Male | 16 (14.0%) | 98 (85.9%) | 114 (55.9%) | |
| | Total | **20 (9.8%)** | **184 (90.2%)** | **204 (100.0%)** | |
| Socio-economic Status | Upper Middle | 0 (0.0%) | 16 (100.0%) | 16 (100.0%) | 0.176 |
| | Lower Middle | 6 (12.5%) | 42 (87.5%) | 48 (100.0%) | |
| | Upper Lower | 0 (0.0%) | 46 (100.0%) | 46 (100.0%) | |
| | Lower | 14 (14.9%) | 80 (85.1%) | 47 (100.0%) | |
| | Total | **20 (9.8%)** | **184 (90.2%)** | **204 (100.0%)** | |
| Crowded Area | Yes | 14 (9.7%) | 130 (90.3%) | 144 (100.0%) | 0.951 |
| | No | 6 (10.0%) | 54 (90.0%) | 60 (100.0%) | |
| | Total | **20 (9.8%)** | **184(90.2%)** | **204 (100.0%)** | |
| H/O TB | Yes | 8 (12.9%) | 54 (87.1%) | 62 (100.0%) | 0.325 |
| | No | 12 (8.5%) | 130(91.5%) | 142 (100.0%) | |
| | Total | **20 (9.8%)** | **184(90.2%)** | **204 (100.0%)** | |
| HTN | Yes | 10 (20.8%) | 38 (79.2%) | 48 (100.0%) | **.003** |
| | No | 10 (6.4%) | 146(93.6%) | 156 (100.0%) | |
| | Total | **20 (9.8%)** | **184(90.2%)** | **204 (100.0%)** | |
| DM | Yes | 6 (10.3%) | 52 (89.7%) | 58 (100.0%) | .869 |
| | No | 14 (9.6%) | 132(90.4%) | 146 (100.0%) | |
| | Total | **20 (9.8%)** | **184(90.2%)** | **204 (100.0%)** | |
| H/O other Co-morbidities | Yes | 10 (27.8%) | 26 (72.2%) | 36 (100.0%) | **.0006** |
| | No | 10 (6.0%) | 158 (94.0%) | 168 (100.0%) | |
| | Total | **20 (9.8%)** | **184(90.2%)** | **204 (100.0%)** | |
| Smoker | Yes | 14 (15.2%) | 78 (84.8%) | 92 (100.0%) | **.018** |
| | No | 6 (5.4%) | 106 (94.6%) | 112 (100.0%) | |
| | Total | **20 (9.8%)** | **184 (90.2%)** | **204 (100.0%)** | |
| Biomass Exposure | Yes | 4 (5.3%) | 72 (94.7%) | 76 (100.0%) | . 092 |
| | No | 16 (12.5%) | 112 (87.5%) | 128 (100.0%) | |
| | Total | **20 (9.8%)** | **184 (90.2%)** | **204 (100.0%)** | |
| Sputum for AFB | Yes | 12 (13.0%) | 80 (87.0%) | 92 (100.0%) | . 158 |
| | No | 8 (7.1%) | 104 (92.9%) | 112 (100.0%) | |
| | Total | **20 (9.8%)** | **184 (90.2%)** | **204 (100.0%)** | |

cure rate was better in males in their study. Although elderly patients had more adverse outcomes in our study but effect was not statistically significant. It could be due to very low number of elderly (10 only) in study group. Old age has been attributed as the reason for adverse outcome in various studies. Atypical clinical and radiological features and other comorbid states and misperception of symptoms may make diagnosis of TB difficult and delayed in elderly patients. The disease may have more advanced disease at the time of diagnosis leading to highest mortality.

All four defaulters in our study belonged to lower socio-economic strata, but no significant relationship between socioeconomic status & adverse outcome could be established in our study. Hypertension & other comorbidities had significant association with poor outcome. In our study diabetes had no effect on treatment outcome. Jiyani MR et al.[10] found that good glycemic control in diabetics was associated with better treatment outcomes. Mundra et al.[11] also did not find any significant effect of diabetes on adverse outcome.

Smokers in our study had significantly higher adverse outcome. 7 out of 8 dead were smokers, while 3 out of 4 defaulters smoke. The finding is similar to Deepti Rathee et al.[12] who found smokers had more severe disease, higher default rate & poorer success rate of treatment. Surprisingly we did not find exposure to biomass as a risk factor for poor outcome. Partly the reason for this could be the females being exposed to biomass which is comparatively a favourable variable for treatment outcome.

41 (27%) out of 152 patients in our study, who successfully completed treatment & were available for follow up after 6 months complained of shortness of breath & or cough. So only 110/152(72.3%) patients were asymptomatic at follow up. It can be understood by the fact that 33 of these 41 patients had residual lesions/ sequelae i.e. fibrosis, calcification & bronchiectatic changes, while another one had destroyed lung on Chest X-Ray. Similar findings were noticed by Chadha et al.[7] Out of 639 patients 2/3rd patients in their study were symptoms free at end of 6months of treatment, rest had symptoms of mild cough and weakness. These findings highlight the fact that just diagnosing & successfully treating tubercular patients is not enough as good number of patients continue to suffer from sequelae of tuberculosis despite successful treatment.

Only one patient (.7%) in our study relapsed & two (1.3%) had died at 6 months follow up. Although 90.1% of patients at two year follow up were asymptomatic in a study by R Prasad et al.[13] but 7.2% relapsed & 2.6% had died. Partly the reason for high rate of post treatment symptoms in our patients could be also high rate of smoking in our study population. 92 out of 204 patients in our study were smokers & 76 had history of biomass exposure.

## 5. Conclusion

It can be concluded that although RNTCP is effective in successfully treating tuberculosis patients. But these patients need to be followed up even after successful treatment as many of them relapse or suffer from sequelae of tuberculosis.

## 6. Limitations of Study

1. Out of 184 patients, 32(17.4%) could not be followed up due to variety of reasons i.e. migration, untraceable, refusal.
2. As study was focused on outcomes, follow up was done till six months only. Post tubercular sequelae may be higher if patients are followed up for longer period.
3. Due to ethical concerns only symptomatic patients at 6 months follow up were subjected to chest X-Ray. If Chest X-ray for all patients can be done, higher number of chest X-ray abnormalities could be found.

## 7. Source of Funding

None.

## 8. Conflict of Interest

None.

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