

# Study on outcome of the treatment of tuberculosis patients registered under Revised National Tuberculosis Control Programme – DOTS strategy

Veeramani G\*, Madhusudhan S

*Assistant professors, Department of Pharmacy, Annamalai University, Annamalai nagar – 608002, TamilNadu, India*

## ABSTRACT

**Background:** India has the highest burden of TB in the world, an estimated 2 million cases annually. It is also estimated by the World Health Organisation (WHO) that 300,000 people die from TB each year in India. Non-adherence to treatment has been recognized as a major problem for cure of TB. [5] **Aims:** To study the outcome of the treatment of tuberculosis patients under Directly Observed Treatment Short course (DOTS) and to determine the risk factors influencing the treatment outcome of tuberculosis. **Methods:** This prospective observational study was carried out in five dots centers, Cuddalore district, TamilNadu. The patients registered from January to December 2014 were included in this study. Data of their treatment outcome was analyzed using standard statistical methods. **Results:** The study included 282 patients among them males were 203(72%) and females were 79(28%). Out of 282 subjects 218(77%) patients had pulmonary tuberculosis and 64(23%) patients had extra pulmonary tuberculosis. Treatment outcome among total 282 subjects was, 161(57%) were completed the treatment, 78(61%) patients got cured, 27(10%) patients were treatment defaulter, 12(4%) patients died and four (1%) patients were failure to treatment. **Conclusion:** Cure rate among New Smear Positive (NSP) patients and retreatment patients was 67% and 43% respectively. Overall treatment Success rate was 85% and the major reason for the failure rate was irregular treatment, defaulting, alcoholism.

**Keywords:** DOTS, Outcome, RNTCP, Tuberculosis

## 1. INTRODUCTION

India has the highest burden of TB in the world, an estimated 2 million cases annually. This accounts for approximately one fifth of the global incidence of TB. It is estimated that about 40% of the Indian population is infected with TB bacteria. The vast majority of infected people have latent TB rather than active TB disease. It is also estimated by the World Health Organisation (WHO) that 300,000 people die from TB each year in India [5]. Directly Observed Therapy Short Course (DOTS) is internationally recommended strategy to ensure cure of tuberculosis [6]. A key component of DOTS strategy is directly observed treatment (DOT); which aims to improve patient adherence to treatment and thus prevents the development of drug resistance [7]. Over the years, there has been increasing emphasis on Directly Observed Treatment short course (DOTS) strategy for TB control in India. Revised National TB control program (RNTCP) adopted DOTS strategy for TB control in India. This has increased success rate of the coverage as well as cure rate. One area of problem is reducing the efficiency of DOTS strategy is default rate. A strict adherence to Directly Observed Treatment is likely to minimize defaults and is therefore essential for the desired treatment success [5].

## 2. MATERIALS AND METHODS

### 2.1. Subjects

One year prospective observational study was carried out at five DOTS centers in cuddalore district,

Tamilnadu. The study was carried out from January to December 2014. All the 282 patients registered at DOTS centers were followed up during their course of treatment to assess treatment outcome. Primary data from each patient included sputum smear report, type of tuberculosis, category of treatment regimen and outcome. Secondary data were collected from various registers maintained under RNTCP and treatment cards of patients. Data included age, gender, form of tuberculosis (pulmonary or extra pulmonary tuberculosis), type of tuberculosis (smear positive or smear negative), category of tuberculosis (new cases or relapse or retreatment cases) and treatment outcome. Treatment outcome of patients was evaluated in accordance with World Health Organization recommendation and classified as: cure, treatment completed, default, treatment failure, death and other. Patients were provided with free TB medications for a period of 6 to 8 months by dots centers. Patients were followed up regularly until completion of treatment.

## 3. RESULTS

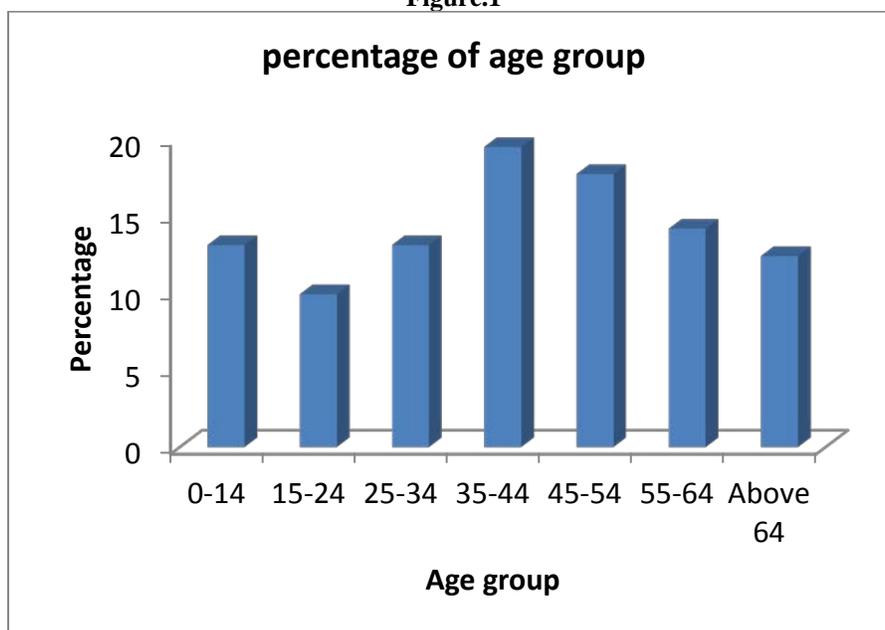
The study included 282 patients out of which 203(72%) were males and 79(28%) were females. The majority of them 217(77%) belonged to economically productive age group Table 1. 218(77%) patients had pulmonary tuberculosis and 64(23%) extra pulmonary tuberculosis Table 2. Among 218 pulmonary tuberculosis patients, New Smear Positive (NSP) patients were 99 and 28 patients were retreatment cases

and their treatment outcome is shown in Table 3. and total success rate was 84.7%. Among extra Treatment outcome of 282 patients is shown in Table 4. Total cure rate was 61.4%, total failure rate was 1.4%, tuberculosis was most common followed by pleural total defaulter rate was 9.5%, total death rate was 4.2% tuberculosis as shown in Table 5.

**Table1. Age-Sex distribution of study population**

| Age      | Male | Female | Total (%) | P- value |
|----------|------|--------|-----------|----------|
| 0-14     | 20   | 17     | 37(13.12) | 0.01     |
| 15-24    | 15   | 13     | 28(9.92)  |          |
| 25-34    | 26   | 11     | 37(13.12) |          |
| 35-44    | 43   | 12     | 55(19.50) |          |
| 45-54    | 38   | 12     | 50(17.73) |          |
| 55-64    | 31   | 9      | 40(14.18) |          |
| Above 64 | 30   | 5      | 35(12.41) |          |
| Total    | 203  | 79     | 282(100)  |          |

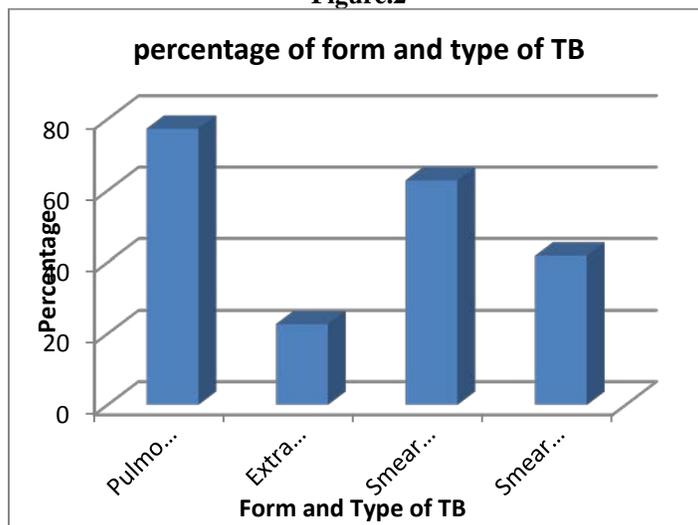
**Figure.1**



**Table2. Form and type of tuberculosis**

| Form and Type of TB | Male | Female | Total (%)  | P-value |
|---------------------|------|--------|------------|---------|
| Pulmonary           | 171  | 47     | 218(77.30) | 0.001   |
| Extra Pulmonary     | 32   | 32     | 64(22.69)  |         |
| Smear Positive      | 102  | 25     | 127(58.25) | 0.42    |
| Smear Negative      | 69   | 22     | 91(41.74)  |         |

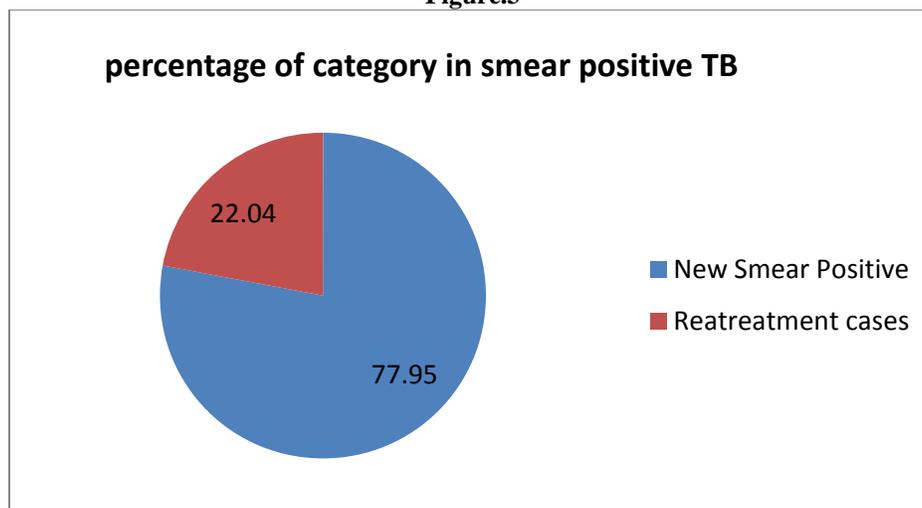
**Figure.2**



**Table3. Treatment outcome in smear positive pulmonary tuberculosis**

| Class              | Cured | completed | Default | Died | Failure | Total (%) | P Value |
|--------------------|-------|-----------|---------|------|---------|-----------|---------|
| New smear positive | 66    | 21        | 7       | 5    | 0       | 99(77.95) | 0.015   |
| Retreatment cases  | 12    | 8         | 4       | 2    | 2       | 28(22.04) |         |
| Total              | 78    | 29        | 11      | 7    | 2       | 127(100)  |         |

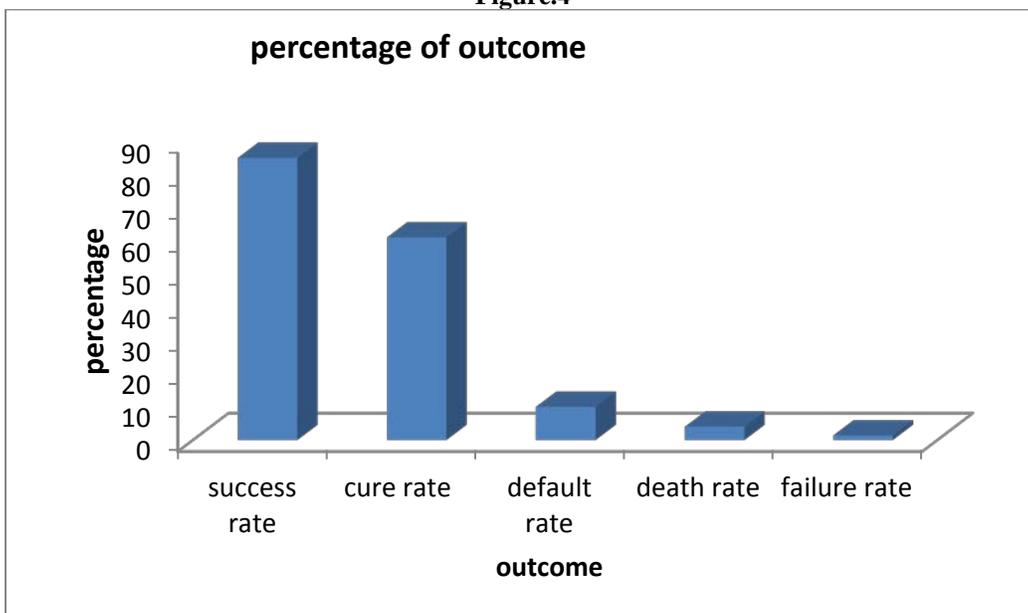
**Figure.3**



**Table4. Treatment outcome of total subjects**

| Treatment Outcome | Results(number of patients) |
|-------------------|-----------------------------|
| Success rate      | 84.75% (239 out of 282)     |
| Cure rate         | 61.41%(78 out of 127)       |
| Default rate      | 9.54%(27 out of 282)        |
| Death rate        | 4.25% (12 out of 282)       |
| Failure rate      | 1.41%(4 out of 282)         |

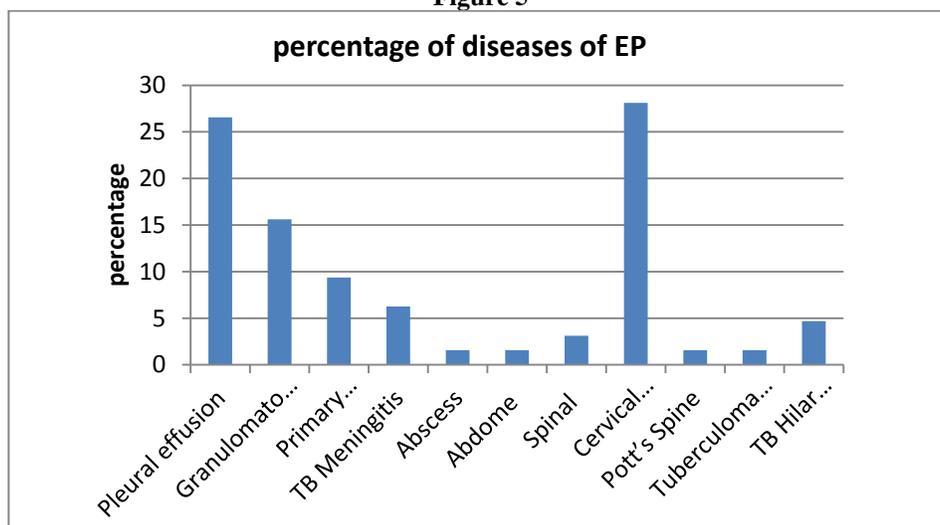
**Figure.4**



**Table5. Extra pulmonary tuberculosis**

| Extra pulmonary TB diseases | Number of patients | percentage |
|-----------------------------|--------------------|------------|
| Pleural effusion            | 17                 | 26.56      |
| Granulomatous Lymphadenitis | 10                 | 15.62      |
| Primary complex             | 6                  | 9.37       |
| TB Meningitis               | 4                  | 6.25       |
| Cold Abscess                | 1                  | 1.56       |
| Abdomen TB                  | 1                  | 1.56       |
| Spinal TB                   | 2                  | 3.12       |
| Cervical Lymphadenitis      | 18                 | 28.12      |
| Pott's Spine                | 1                  | 1.56       |
| Tuberculoma Brain           | 1                  | 1.56       |
| TB Hilar adenitis           | 3                  | 4.68       |
| Total                       | 64                 | 100        |

**Figure 5**



#### 4. DISCUSSION

The great burden of tuberculosis incidence and mortality in developing countries is in adults aged 15-60 years which includes the most socio-economically productive members of the society such as parents, workers, community leaders etc. Due to their age factor and socio-economic dependence of family they involve themselves in earning and get exposed to other cases in community [8]. In present study tuberculosis was seen more in males compared to females. Similar results were seen in study by Chennaveerappa PK et al [9] and Mir Azam Khan et al [11], reported equal number of cases in both sexes. Tuberculosis mostly affects the lungs, but it may affect other organs of the body.

The study shows that pulmonary tuberculosis accounted for 218 cases (77.3%) of the total burden of the disease in the study population, while the extra pulmonary tuberculosis accounted for 64(22.7%) cases. This data differs from the national figure which states that 85-90% of cases are pulmonary tuberculosis and 10-15% of cases are extra pulmonary tuberculosis [12], out of total new cases.

3. Among 58 NSP patients treatment outcome was, 66 (67%) patients got cured, 21(21%) patients were completed, and 7 (7%) patients were defaulters. When compared to a study treatment outcome was poor in a study done by Chennaveerappa PK et al [9] the outcome of our study was poor and When compared to our study treatment outcome was poor in a study done by Moharana et al [13]. Among 28 retreatment cases treatment outcome was, 12(43%) patients got cured, 8(29%) patients were completed, 4(14%) were defaulters, two patients were died and two patients were failure to treatment. Success rate was higher in our study when compared to a study done by S.L. Chadha and R.P. Bhagi [14].

In our study treatment outcome among total 282 subjects was, 161 out of 282(57%) patients were completed the treatment, 78 out of 127 (61.4%) patients got cured, 27(9.5%) were treatment defaulters, 12(4.2%) patients died, 4(1.4%) patients were treatment failure. The overall success rate was 84.7% (239 out of 282 cases), which included the outcome of; smear negative pulmonary tuberculosis and extra pulmonary tuberculosis.

In a study done by Chennaveerappa PK et al [9], similar success rate was observed. Lower cure rate was observed in our study when compared to the studies done by Chennaveerappa PK et al [9] and Menke et al [15]. Among 12 patients who died, three patients were made suicide attempt, others nine patients were died because of respiratory failure. Among 27 defaulters three patients had co-morbid HIV infection, 14 patients were alcoholic, eight patients were migrated and two patients went to private consultant during the course of treatment. Four patients were treatment failure due drug resistance

and category IV regimen was started. Cure rate among NSP cases and retreatment cases was less than RNTCP norm. In a study done by the Chennaveerappa PK et al [9] was reported more cure rate among smear positive tuberculosis patients compared to our study.

#### 5. CONCLUSION

Cure rate among new smear positive cases and retreatment cases was 67% and 43% respectively. 21% of NSP patients and 29% of smear positive retreatment patients were successfully completed the treatment but the sputum at the end of treatment could not be collected from patients due to migration and lack of co-operation. The overall success rate was 84.7%; the reason for the failure rate was irregular treatment, defaulting and alcoholism.

#### Key message:

The highest prevalence was seen in the economically most productive age group (15-60 years).

Pulmonary tuberculosis is more common in government dots centers.

Alcohol addiction and migration play a major role in drug defaulting.

#### Acknowledgements

The authors thank Mr. N. Kamalakannan (Senior Treatment Supervisor) for maintaining patient's treatment records. The authors are grateful to the Deputy Director (TB), Cuddalore district, TamilNadu.

#### 6. REFERENCES

- [1] Murray CJ, Lopez AD. Mortality by cause for eight regions of the world; global burden of disease study. *Lancet*. 1997; 349: 1269-1276.
- [2] Murray CJ, Lopez AD. Regional pattern of disability free life expectancy and disability-adjusted life expectancy; global burden of disease study. *Lancet*. 1997; 349: 1347-1352.
- [3] Naing NND, Este C, Isa AR, Salleh AR, Bakar N, Mahmood MR. Risk factors to poor compliance with anti-TB treatment among tuberculosis patients. *South East J Trop Med Public Health*. 2001; 32: 369-382.
- [4] Tuberculosis facts 2010/2011 Geneva: World Health Organization; 2010.
- [5] [http://www.tbncindia.org/pdfs/TB India 2010.pdf](http://www.tbncindia.org/pdfs/TB%20India%202010.pdf)
- [6] Global tuberculosis Control, Surveillance, Planning, Financing- WHO Report 2005: WHO/HTM/TB/2005. 49, WHO Geneva; 2005.
- [7] Trebueq A, Reider HL. Two excellent management tools for national tuberculosis programmes; history of prior treatment and sputum status at two months. *Int J Tuberc Lung Dis*. 1998; 2: 184-186.
- [8] Managing the RNTCP in your area, a training course: Modules 5-10, Central TB Division, DGHS, MOHFW, New Delhi, July 1999.
- [9] Chennaveerappa PK, Sddharam SM, Halesha BR, Vittal BG, Jayashree N. Treatment outcome of tuberculosis patients registered at dopts centre in ateaching hospital, south india, 2011;2(2): 487-489
- [10] Diel R, Niemann S. Outcome of tuberculosis treatment in Hamburg: a survey 1997-2001. *Int J Tuberc Lung Dis*. 2003; 7(2): 124-131.
- [11] Khan MA, Basit A, Ziaullah, Javaid A. Outcome of tuberculosis patients registered during 2007 in major teaching hospitals of Peshawar. *JPMI*, 2009; 23(04):358-362.

- [12] Central TB Division, Directorate General of Health Services, Ministry of Health and Family Welfare, New Delhi. RNTCP TB status Report. 2007; 1: 10-13.
- [13] Moharana PR, Satapathy DM, Sahani NC. An analysis of treatment outcome among TB patients put under dots at a tertiary level health facility of Orissa. *Jcomm Med.* 2009; 5(2): 5-8.
- [14] Chadha SL, Bhagi RP. Treatment outcome in tuberculosis patients placed under directly observed treatment short course- A cohort study. *Ind J Tub.* 2000; 47:155-158.
- [15] Menke B, Sommerwreck D, Schaberg T. Result of Therapy in pulmonary tuberculosis. Outcome Monitoring in Northern lower Saxony. *Pneumologie* 2000; 54: 92-96.
- [16] Santha T, Garg R, Frieden TR, Chandrasekaran V, Subramani R, Gopi PG, Selvakumar N, Ganapathy S, Charles N, Rajamma J, Narayanan PR. Risk factors associated with default, failure and death among tuberculosis patients treated in a DOTS programme in Tiruvallur District, South India, 2000: *Int J Tuberc Lung Disease.* 2002; 6(9): 780-788.
- [17] Wobeser W, Yuan L, Naus M. Outcome of pulmonary tuberculosis treatment in the tertiary care setting- Toronto 1992/93. *CMAJ* 1999; 160: 789-794.