ISSN: 0975-5772

Bhimaray Krishnagoudar et al / Journal of Pharmaceutical Science and Technology Vol. 3 (12), 2011,757 - 761

# An Evaluation of Tuberculosis Cases: A Retrospective Study

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## Abstract:

Tuberculosis is a contagious infection caused by air borne bacteria Mycobacterium tuberculosis. India accounts for one-fifth of the global TB incident cases, each year nearly two million people in India develop TB.<sup>1</sup>

It is a retrospective record based study carried at AH & RC (Adichunchanagiri Hospital & Research Centre) tertiary care teaching hospital, B.G Nagara.

Out of 120 patients diagnosed, the male to female ratio is 2.5:1, Pulmonary TB cases were more i.e. 85 (75.83%) and new smear positive cases were 62 (51.67%). Total 67 (55.83%) patients were categorized in CAT-I, 25 (20.83%) patients in CAT-II and 28 (23.33%) in CAT-III.

The Treatment Completion Rate (TCR) and rate of cure was not known since centers failed to provide proper feedback to which patients were transferred. So, for transferred TB cases a better system of follow up should be done in order to know about the TCR and rate of cure.

Key Words: RNTCP/DOTS centre, Category, Tuberculosis, TCR (Treatment Completion Rate).

#### **Introduction:**

Worldwide, Mycobacterium tuberculosis remains the leading infective cause of mortality and morbidity <sup>1</sup>. Each year about 8 million people worldwide develop TB.Of these, 95% occur in developing countries. India accounts for about 20% of the global burden of TB. Nearly 2.2 million people develop TB and about 3.5 lakh die every year <sup>2</sup>.

Tuberculosis is a social disease with medical implications. It has always occurred disproportionately among disadvantaged populations such as the homeless, malnourished, and over-crowded. Within the past decade it also has become clear that the spread of HIV infection and the immigration of persons from areas of high incidence have resulted in increased numbers of tuberculosis cases<sup>3</sup>.

The National Tuberculosis Control Programme (NTP) was implemented in 1962. However, when reviewed in 1992, after three decades of implementation, the NTP was shown to have made no epidemiological impact, mainly due to poor case finding and low treatment completion rates. As a result, the Government of India (GoI) in 1993 developed the Revised National Tuberculosis Control Programme (RNTCP) based on the internationally recommended Directly Observed Treatment – Short course (DOTS) strategy <sup>5</sup>.

Hospital based studies show that most of the patients admitted to the hospital are middle aged males. Pulmonary TB is the most common form of TB (more than 85% of all TB cases) while Extra-pulmonary TB can affect almost any organ in the body. The prevalence of TB infection in India is 30%. As per statement of Director General of WHO, DOTS strategy was most important breakthrough of the decade in terms of lives saved. The W.H.O. recommended DOTS strategy (Directly Observed Treatment Short Course) was covered in the entire India by 24<sup>th</sup> March 2006 <sup>5</sup>. The past decade has seen a rapid expansion of directly observed treatment, short-course (DOTS) centers throughout India, under the guidance of the Revised National Tuberculosis Control Programme (RNTCP) <sup>1</sup> Continued success of the programme, however, remains a daunting task as there has been very little co-ordination between the RNTCP, faculties of medical schools and health providers in the private sector. In medical schools, training on TB and HIV/AIDS does not focus on the public health aspects relating to prevention and control of these diseases <sup>4</sup>. Pulmonary Tuberculosis (PTB):

The essential basis of diagnosis of pulmonary tuberculosis was three sputum smear examinations for M. tuberculosis (two spot and one early morning sample) according to the RNTCP guidelines.

Extra pulmonary Tuberculosis (EPTB):

Was diagnosed by the following criteria: (I) constitutional and organ specific clinical features depending upon the site of TB; (ii) radiographic features suggestive of TB; (iii) microbiological and /or histopathological diagnosis depending on the site (not an essential criteria for meditational lymph nodes and pleural effusion) and (iv) a satisfactory response to anti-tuberculosis treatment. Categorization of Patients:

Patients were categorized into various treatment categories as per the RNTCP guidelines. Briefly, new sputum smear positive and seriously ill sputum smear negative pulmonary TB and extra pulmonary TB patients (Category I) were treated during intensive phase with four drugs: ionized (H), rifampicin (R), pyrazinamide (Z) and ethambutol (E) for two months followed by continuation phase of four months of two drugs, H and R. New sputum smear negative pulmonary TB and not seriously ill extra pulmonary TB patients (category III) were treated during the intensive phase with three drugs, H,R,Z for two months followed by continuation phase of four months of two drugs, H and R. Previously treated patients (category II) were treated during the intensive phase with five drugs H,R,Z,E and streptomycin (S) of initial two months and one month with four drugs as previously mentioned except S, followed by the continuation phase of five months with H, R and E. Smear positive patients whose smear was positive at the end of intensive phase received another month of intensive phase treatment. During the intensive phase every dose was given thrice weekly on alternate days under direct observation. Medications for continuation phase were packaged into weekly blister pack, the first dose of which was given under direct observation. The empty blister pack was returned the following weeks as evidence that the patient had taken the medicines <sup>4</sup>.

# **Objectives:**

- 1. To estimate the number of New Smear Positive (NSP) case detected during diagnosis.
- 2. To study the age & sex distribution of TB patient diagnosed.
- 3. To study the variants of TB i.e. New Smear Positive, New Smear Negative, and Extrapulmonary TB.
- 4. Categorization of all TB cases diagnosed at DOTS center.

# **Experimental methods:**

This is a retrospective record based study carried out in the tertiary care teaching hospital of the rural area of south India. Adichunchanagiri is a 750 bedded tertiary care teaching hospital affiliated to Adichunchanagiri institute of medical sciences. RNTCP being a part of AH & RC, the patients diagnosed with TB are referred to the DOTS clinic where they are registered and treated according to RNTCP guidelines.

Data collection: Prior to collection of data from the RNTCP centre, permission was obtained from the medical superintendent of the hospital by explaining him the nature of the study. Then a total of 120 TB patients registered in the DOTS clinic from September 2009 to August 2010, were included in the study. Patients' registration numbers were used to obtain corresponding files from the medical records department. From each medical case file, the patient's history, physical findings, chest radiographs and reports of laboratory investigations were reviewed to obtain the necessary information about diagnosis of TB. The patients were divided into EPTB and PTB groups. The two groups were compared in respect to age, sex, and into case categories (new case or previously treated case). The new smear positive and smear negative cases were recorded in the suitable tabular form.

#### **Results:**

Out of 120 patients diagnosed, the male to female ratio was 2.5:1, and 29 are from age group of 40 to 49 years were more. Pulmonary TB cases were more i.e. 85 (75.83%) when compared to extra pulmonary i.e. 35 (29.17%), new smear positive cases were 62 (51.67%) and new smear negative cases were 58 (48.33%). Total 67 (55.83%) patients were categorized in CAT-I, 25 (20.83%) patients in CAT-II and 28 (23.33%) in CAT-III.

Table-I: Age and Sex distribution of tuberculosis patient.

|             | Total patient diagnosed at RNTCP of |            |  |  |
|-------------|-------------------------------------|------------|--|--|
| Age (years) | AH & RC                             |            |  |  |
|             | Male                                | Female     |  |  |
| 0 - 9       | 05                                  | 03         |  |  |
| 10 - 19     | 02                                  | 02         |  |  |
| 20 - 29     | 10                                  | 03         |  |  |
| 30 - 39     | 17                                  | 08         |  |  |
| 40 - 49     | 20                                  | 09         |  |  |
| 50 - 59     | 13                                  | 06         |  |  |
| 60 - 69     | 14                                  | 02         |  |  |
| 70 - 79     | 05                                  | 01         |  |  |
|             | 86(71.66%)                          | 34(28.33%) |  |  |
| Grand total | 12                                  | 20         |  |  |

Table 1 show that 71.66% males were diagnosed for TB compared to 28.33% females. TB patients diagnosed up to age of 40-49 years were more i.e. 29(24.16%) out of this 20 male and 09 female population respectively as compared to other decades of age and sex group. Also there were many patients diagnosed in the age group between 30-70 years.

Table-II: Quarterly report of sputum evaluation (Sep-09 to Aug -10)

| Table 11: Quarterly report of sputum evaluation (Sep 0) to flug 10) |                          |        |                             |        |       |  |
|---|--------------------------|--------|-----------------------------|--------|-------|--|
| Quarter   | New smear positive (NSP) |        | New smear<br>negative (NSN) |        | Total |  |
|   | Male                     | Female | Male                        | Female |       |  |
| Sep-09 to Nov-09  | 11                       | 04     | 12                          | 01     | 28    |  |
| Dec -09 to Feb -10  | 17                       | 02     | 12                          | 06     | 37    |  |
| Mar-10 to May-10  | 08                       | 02     | 04                          | 09     | 23    |  |
| June-10 to Aug -10  | 14                       | 04     | 08                          | 06     | 32    |  |
| Grand total   | 50                       | 12     | 36                          | 22     | 120   |  |

Table II shows that there was an increase in diagnosis of new smear positive case in the centre. Average diagnosis of new smear positive was 12.92%, with the male population being 50 (41.67%) and female population being 12 (10%). During the period of second quarter i.e. December-2009 to Feburary-2010 the strength being 19 (30.65%) out of the total 62 new smear positive population diagnosed.

Table -III: Pulmonary and Extrapulmonary TB

| Tubic 1111 I dimondify and Entrapaintonary 12 |                 |              |        |                    |        |  |
|---|-----------------|--------------|--------|--------------------|--------|--|
| Age   | Total number of | Pulmonary TB |        | Extra pulmonary TB |        |  |
| (years)                                       | diagnosed TB    | Male         | Female | Male               | Female |  |
| 0 – 9   | 08              | 03           | 02     | 02                 | 01     |  |
| 10 - 19                                       | 04              | 02           | 01     | 00                 | 01     |  |
| 20 - 29                                       | 13              | 05           | 03     | 05                 | 00     |  |
| 30 - 39                                       | 25              | 14           | 06     | 03                 | 02     |  |
| 40 - 49                                       | 29              | 14           | 03     | 06                 | 06     |  |
| 50 – 59                                       | 19              | 13           | 02     | 00                 | 04     |  |
| 60 - 69                                       | 16              | 11           | 02     | 03                 | 00     |  |
| 70 - 79                                       | 06              | 04           | 00     | 01                 | 01     |  |
| Total   | 120             | 66           | 19     | 20                 | 15     |  |

Table III shows about the type of TB diagnosed. The most cases found out were the pulmonary TB cases with 85 (70.83%) and extra pulmonary cases being 35 (29.17%). The pulmonary TB with age group of 30 -39 being more i.e. 20 (23.5%) and extrapulmonary TB with the age group of 40 to 49 with 12 (34.29%) cases.

Table-IV: Category wise distribution of TB patients

|                 |       | 0 0    |        |        |         |        |       |
|-----------------|-------|--------|--------|--------|---------|--------|-------|
| Categorization  | CAT-I |        | CAT-II |        | CAT-III |        | Total |
|                 | Male  | Female | Male   | Female | Male    | Female | Total |
| Total diagnosed | 53    | 14     | 20     | 05     | 13      | 15     | 120   |

Table IV show that 67(55.83%) patients were in Category I, 25(20.83%) patients were in Category II and 28(23.33%) patients were in Category III. AH&RC being a tertiary care centre, more number of seriously ill patients were placed in Category I.

## **Discussion:**

There is increase in smear positivity due to the sensitization workshop organized for staff, postgraduates, nurses & interns. Out of 120 cases diagnosed, Category –I patients were 67 (55.83%) which include new smear positive, new smear negative and extra pulmonary cases. In 120 patients the age group between 30 to 70 is predominant with tuberculosis where the patient between age of 40 to 49 being more in number with 29 (24.16%) and pulmonary TB between 30 - 39 age i.e. 20 (23.5%) and extrapulmonary TB with 40 to 49 age i.e. 12 (34.29%) cases.

The patients whose smear was examined for TB showed the results with both 'smear positive' and 'smear negative'. But, for 'smear negative' patients empirical treatment with anti-TB drugs was given. As the diagnosed patients did not stay in the AH & RC centre until the treatment completion, such patients were put on DOTS and referred to their nearest peripheral RNTCP centre for the treatment completion. So, the inpatients data in the AH & RC centre was not available. The feedback of patients referred to the peripheral centers was not available due to lack of proper communication from the peripheral centers and also lack of regular follow up from the patients which hindered the treatment completion rate <sup>6</sup>. There is a variation in the cases diagnosed at the centre due to poor health literacy among the population where most of the people are illiterate, even some of the patients gave wrong address or some have shifted from the previous residing area.

### Conclusion:

RNTCP/DOTS regimens were found to be effective to diagnose and treat even the complicated cases of TB. The TCR and rate of cure was not known since all patients were transferred to their nearest peripheral DOTS Centers and those centers failed to provide proper feedback. So, for transferred cases a better system of follow up should be done in order to know about the TCR and rate of cure.

# Acknowledgement:

We thank Lokesh AC, TB health visitor, Gopal DP, lab technician who helped in providing tuberculosis case records. Thanks due to Dr. M Shivanna, Medical superintendent; also we thank Dr. B Ramesh Principal SAC College of Pharmacy.

#### **References:**

- 1. CT Sreeramreddy, KV Panduru and SC Verma. Comparison of pulmonary and extrapulmonary tuberculosis in Nepal-a hospital based retrospective study, BioMed central infectious disease: (2008).
- 2. D Acharya, JP Majra. A clinical-epidemiological study of tuberculosis among hospitalized cases in Dakshina Kannada district of Karnataka, NTI Bulletin, 43/3 & 4, 43-46: (2007).
- 3. American thoracic society. Diagnostic standards and classification of tuberculosis in adults and childrens, American journal of respiration and critical care medicine, vol-161: 1378-1395; (2000).

- 4. Sharma SK, Lawaniya S, Lal H, Singh UB, and Sinha PK. Dots centre at a tertiary care teaching hospital; lessons learned and future directions, the Indian journal of chest disease and allied science, vol-46: 251-256; (2004).
- 5. PD Baburao, PS Bhaskar and PV Deepak. Study of tuberculosis cases under RNTCP attending designated microscopy centre at Pravara rural hospital, Loni, Pravara Med Rev 4(4): (2009).
- 6. Ganesh kumar S, Harsha kumar HN, Ramakrishna Rao, Jayaram S and Kotin MS. Trends of tuberculosis cases under DOTS strategy in Dakshina kannada district of Karnataka, India; Issue and challenges, Iranian journal of public health, vol-38: 72-76; (2009)