

## TREATMENT AND DIAGNOSTIC PRACTICES FOLLOWED FOR TB PATIENTS UNDER REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME IN THE PROJECT AREA OF BANGALORE MAHANAGARA PALIKE- A COHORT STUDY

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### Summary

The study was undertaken to know the clinical, bacteriological and radiological status of Tuberculosis (TB) patients after 3 – 5 years of treatment under Revised National Tuberculosis Control Programme (RNTCP) in project area Bangalore Mahanagara Palike (BMP). Out of the 454 TB patients from three cohort periods of 1994-96, only 178 (39.2%) could be interviewed as 220 (12.06%) could not be located due to incorrect address or migration and 56(12.3%) had died. Of the 178 patients interviewed, 40% had persistent cough and 44% had persistence of radiological shadow inspite of completion of treatment.

**Key words: Persistence of symptom, X-ray activity, Address verification**

### Introduction

Revised National Tuberculosis Control Programme (RNTCP) was implemented in 1993 under phase I covering a population of 2.5 lakhs which included the Shanthinagar area of BMP. Subsequently, the coverage was expanded to another four dispensaries and one Medical College covered under that area.

Over a period of three years (1994 to 1996), a total of 454 TB patients were put under three categories of treatment consisting of Short course Chemotherapy (SCC) regimens under Direct Observation as recommended under RNTCP<sup>1</sup>. The emphasis was to provide drugs under the direct supervision of a Direct Observation of Treatment (DOT) provider. On an average, it

was observed that the cure rate was on the lower side of the expectation (<80%). This low cure rate prompted for a study of treatment and diagnostic practices adopted by BMP in early period of the pilot phase.

### Objectives

1. To study bacteriological, radiological and clinical status of TB patients registered under RNTCP in BMP from 1994 – 1996 following 3 – 5 years of completion of treatment under Directly Observed Treatment Shortcourse (DOTS).
2. Verifying the authenticity of the address recorded to ascertain the factor contributing to low cure rate.

### Methodology

Four hundred fifty four (454) TB patients diagnosed and put on treatment from the pilot project area of BMP for the three cohort periods 1994, 95 & 96 formed the study group. TB registers from the 7 Tuberculosis Units of Bangalore Mahanagara Palike (BMP) and treatment cards from the health facilities covered under the area were the source of information for the address, follow-up examination and the treatment outcome of patients under the study. This study was undertaken between January 1999 to March 2000. Interview schedules were developed to collect information on diagnosis, treatment, DOTS practices and subsequent treatment.

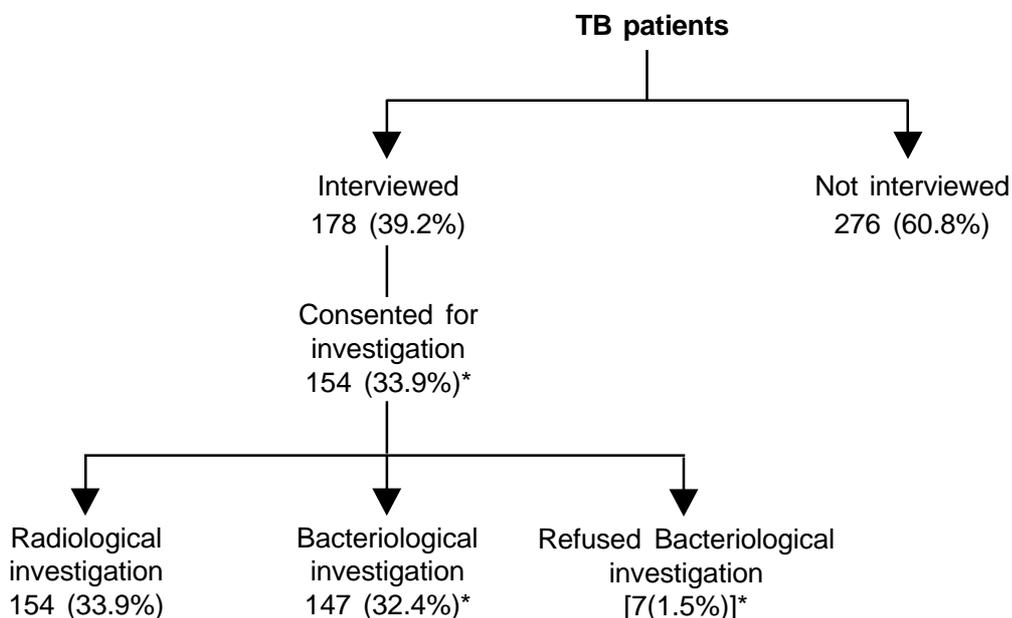
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The residential locations of all the TB patients were mapped out, interview schedules of those patients who were available at the time of contact were filled up by the Health Visitors of National TB Institute (NTI). A plan of action was developed for getting patients to NTI for the bacteriological and radiological examinations. Clinical evaluation was undertaken for extra pulmonary cases. A maximum of 4 visits were made to trace the patients before recording them as "not available for interview". Bacteriological examination consisted of smear microscopy, Culture by modified petroff's and Drug Susceptibility testing by Minimum Inhibitory

Concentration method for two specimens. Chest X-rays were taken and read by two readers (large X-ray film). The readings were classified as normal, active, probably active, inactive and non-tuberculous.

### Results

Among 454 patients diagnosed, registered and treated from January 1994 to December 1996, only 178 (39.2%) could be traced and interviewed as per the addresses provided and the break-up of these patients were 25 in 1994, 30 in 1995 and 123 in 1996 from cohort period respectively.



(\*Percentage in relation to 454 patients registered during the study period)

Of the 178 patients interviewed, 156 were pulmonary cases (87.6%) and 22 (12.4%) extra-pulmonary cases. Male to female ratio among 178 patients was almost 1:1. Among 178 interviewed, 66 (37.1%) were initially sputum smear positive and 90 (50.5%) were smear negative

X-ray positive and 22 (12.4%) were extra pulmonary. A total of 97 (54.5%) patients had Category I, 10 (5.6%) were on Category II and 71 (39.9%) on Category III treatment. 276 (60.8%) patients could not be interviewed.

Among the 178 patients interviewed, 59 (33.1%) had recalled giving all 3 sputum samples for examination at the time of initial sputum examination before starting treatment. 46 (25.8%) had stated to have given two samples, 34 (19.1%) had given one sample and 39 (22.0%) could not recall whether they had given any sample. As regards the follow-up examination at the end of the intensive phase, 115 out of 178 (64.6%) had undergone the examination as per the records in the TB register.

## Symptoms elicitation

Evaluation of pulmonary symptoms revealed that 72 (40%) out of the 178 patients interviewed had one or more symptoms like

cough, fever and chest pain inspite of having taken full course of treatment and being declared cured / treatment completed.

## Bacteriological investigation

**Table – 1**  
**X-ray status vs Culture Results**

	Culture result			
	Negative	Positive	Contaminated or not done	Total
<b>Normal</b>	72	01	00	<b>73</b>
<b>Active / probably active</b>	13	06	01	<b>20</b>
<b>Inactive</b>	39	06	01	<b>46</b>
<b>Non-tuberculous</b>	07	01	00	<b>08</b>
<b>Total</b>	<b>131</b>	<b>14</b>	<b>02</b>	<b>147</b>

Among 147 patients who provided sputum for bacteriological examination, 14 (9.5%) were culture positive. Six out of 14 were smear positive (Table 1). After perusal of the treatment card and information elicited during interview for the culture positive patients, it was observed that they had taken fairly regular treatment and the follow-

up examinations were also carried out as per the recommended norms under RNTCP. Five out of 14 were found to harbour sensitive bacilli to all the drugs, 5 were found to be resistance to both INH & Rifampicin and seven showed resistance to either INH or Rifampicin.

## Radiological investigation

**Table – 2**  
**Correlation of X-ray reading between two readers**

	Reader 1				
	Negative	Active/ probably active	Inactive	Non-tuberculous	Total
<b>Normal</b>	69	01	05	04	<b>79</b>
<b>Active / probably active</b>	02	10	08	00	<b>20</b>
<b>Inactive</b>	07	09	33	02	<b>51</b>
<b>Non-tuberculous</b>	02	00	00	02	<b>04</b>
<b>Total</b>	<b>80</b>	<b>20</b>	<b>46</b>	<b>08</b>	<b>154</b>

Chest radiograph taken at NTI were read by two readers and the X-ray evaluation showed that there was an agreement in 114 (74%) X-rays read by both the readers, 44% of the X-rays were classified as inactive, probably active or non-tuberculous by either of the readers (Table – 2). Out of the 14 culture positive patients, X-rays of 6 were read as active / probably active and 6 were read as inactive, one as normal and one non-tuberculous. Fifty nine (59) had persistence of shadow inspite of being culture negative.

### **Patients not interviewed**

Among 276 patients not interviewed, the main reasons for the inability to contact them was as follows:

- Residence could not be located for 164 (36.1%) as address was incorrect.
- 56 (12.3%) had migrated.
- In all 56 deaths had taken place among the 454 patients registered of which 29 (6.38%) occurred during the course of treatment which were recorded in the TB register and another 27 (5.94%) came to light during verbal autopsy.

The information regarding sex, age, initial sputum status, treatment aspects of 29 patients who died during the course of treatment as indicated in the treatment card and TB register showed that 25 (86.2%) were males and 4 (13.8%) were females, of which 18 (62.1%) were aged less than 50 years. 21 (72.4%) were smear positive and 8 (27.6%) smear negative at the time of initial diagnosis. The treatment regimen offered to them were Cat. I, Cat. II, and Cat. III for 16, 11 and 2 patients respectively. Data on category of treatment were not available for two patients both in the treatment card and the TB register.

The information regarding age, initial sputum status, treatment aspects of 27 who died after completion of treatment compiled from the treatment card and TB register showed that 21 (77.8%) were males and 6 (22.2%) females of which 15 (55.6%) were <50 years. As regards

the initial smear status of the patients, 15 (55.6%) were smear positive, 11 (40.7%) smear negative and 1 (3.7%) extra-pulmonary. The treatment regimen offered to them were Cat. I, Cat. II and Cat. III for 16, 4 and 7 patients respectively.

### **Discussion**

Implementation of TB control programme in the pilot project areas of BMP posed a challenge, as BMP was never involved in TB control activities until 1993. Diagnostic network for TB was practically non-existent under the National Tuberculosis Control Programme; the TB services were limited to referring patients for diagnosis and treatment from few of the government health institutions to Lady Willingdon State TB Demonstration Centre. The BMP undertook the onerous task of implementing RNTCP in 1993 through the existing network of maternity homes and dispensaries attached to those maternity centres.

In the early phase of implementation, many patients were supplied anti-TB drugs on a weekly / fortnightly basis with instructions to consume the drugs at home thrice a week. This procedure was probably resorted due to non-availability of manpower at different levels and also due to inability of establishing DOTS centers nearer to the patient's residence. In such circumstances, it was thought that it would be interesting to study the status of patients in terms of bacteriological, X-ray and clinical status after a gap of 3 – 5 years following treatment completion. In spite of repeated efforts by the Health Visitors including that by the Social Investigators, only 40% of the registered patients could be traced. The reasons for this shortfall can be partially attributed for a long gap of about 2 years following the completion of treatment and the possibility of frequent shifting of the residence in the metropolis and also migration, to a certain extent and to death<sup>2</sup>.

Recording wrong address have also contributed to the shortfall. Address elicitation is an art which has been clearly demonstrated in a study carried out by Tuberculosis Research Centre, Chennai wherein the registering clerk had

recorded address correctly only in 66% of the 355 patients<sup>2</sup>. Under RNTCP, if verification of the address by the Sr. Treatment supervisor is done before starting treatment, the above situation could possibly be averted to a large extent. As RNTCP was in its infancy during 1994-96, proper procedure for verifying the address before commencing treatment by the Sr. Treatment Supervisor was not followed as per the guidelines of the RNTCP. The follow-up examination carried out was only to the extent of 60% as per the scrutiny of the records and also during interview, the recall regarding initial and follow-up examination was poor for most of the patients. It is an interesting observation that more than 40% of the patients continued to have symptoms inspite of being cured / treatment completed. Similar findings have been reported in the follow up studies done by at NTI<sup>3,4 & 5</sup>.

Another important findings is that 44% of the subjects had persistence of a radiological shadow inspite of having completed treatment and they were read as active / probably active / non-tubercular. These findings have again demonstrated the inherent limitations of interpretation of activity of the lesion. The disagreement on the question about the presence of any pulmonary abnormality has been brought out well in the international study on X-ray classification<sup>6</sup>. In another study, 5% of smear positives were reported as having X-ray normal 17% probably non-tubercular and 24% as inactive lesion<sup>3</sup>. However, in the present study there is one culture Positive case with x-ray read as normal. The pattern of drug consumption among the 14 patients who were culture positive were fairly regular of which one patient was from 1994 cohort, 2 from 1995 cohort and 11 were from 1996 cohort. Therefore, this will have to be assumed to be relapse, but five out of them were harboring MDR strains, which is probably a pointer to the concealed irregular treatment or due to non DOTS. As regards death, 6.3% deaths took place during the course of treatment and 5.8% after completion of treatment. This is somewhat higher than the national average under RNTCP<sup>7</sup>.

## Conclusion

The results of this study could be of immense benefit for the newly implemented RNTCP districts, particularly in the urban areas. The status of TB patients after a gap of 1- 2 years would provide an insight into the practices adopted by RNTCP, though with limitations of recall bias. This study like many other earlier studies shows the importance of recording correct addresses for better compliance. X-ray reading has its own limitations in judging the activities of the lesion. Persistence of symptoms among patients having X-ray shadows does not necessarily mean that the patients have active disease.

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