



ASSESSMENT OF HEALTH STATUS OF SUCCESSFULLY TREATED CATEGORY I PATIENTS UNDER RNTCP PROGRAM, FIVE YEARS AFTER TREATMENT COMPLETION - A RETROSPECTIVE COHORT STUDY FROM A COASTAL DISTRICT OF INDIA

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ABSTRACT

Background: Tuberculosis remains a major public health problem worldwide and also in India. In spite of RNTCP being a comprehensive programme for effective management and control of tuberculosis, efficacy of DOTS regimen is questioned by private practitioners.

Methods: A retrospective cohort study was carried out in a coastal district of India to assess the health status of successfully treated Category I patients under RNTCP program, five years after treatment completion. An interview was conducted with all the available subjects at their residence using a semi-structured pre-tested interview.

Results: Out of 224 registered new sputum positive patients, 177 cases were successfully treated during the recruiting year, accounting for a success rate of 79%. Of the 177 treated patients, 118 were traceable during the study period, out of which 100 subjects had survived after 5 years and were available for the interview. Recurrence of TB was reported in 2 patients during the follow up period.

Conclusion: This five years follow up study shows a good long term success rate of TB patient's treatment. Hence, it reaffirms the scientific basis of RNTCP policy of DOTS regimen to be the right strategy for TB control.

KEY WORDS: RNTCP, DOTS, tuberculosis, current status, NSP patients

INTRODUCTION

India's Revised National Tuberculosis Control Programme (RNTCP), based on the 'Directly observed therapy, short course' (DOTS) approach, a comprehensive approach to tuberculosis (TB) control, is one of the most cost-effective health interventions available.^{1,2} The Revised National TB Control Programme (RNTCP), based on DOTS strategy, was launched in 1997 and expanded

across the country in a phased manner with support from the World Bank and other development partners. The program is covering the entire nation since March 2006 reaching over a billion population (**1.16 billion**) in 632 districts / reporting units. In 2008 **1.51** million patients were put on treatment and in 2010 **1.52** million patients have already been placed on treatment.³

The RNTCP has been remarkably successful and has achieved high cure rates of 80–85% nationally.³ It has not only improved case-finding, but also made possible the availability of uninterrupted short-course chemotherapy and increased the cure rate for the disease. However, private practitioners still question the efficacy of DOTS regimen because the efficacy of treatment regimens in tuberculosis is judged not only by a high cure rate, but also by a low rate of relapse on follow up.⁴ Although government hospitals and health care providers are increasingly adopting the DOTS regimen for treating tuberculosis, very few private practitioners have followed suit in India.

DOTS was implemented in July 2004, in Udupi district, a coastal region in the state of Karnataka. Literature search did not reveal any follow-up study to evaluate the program with respect to the outcome of successfully treated new sputum positive (NSP) TB patients, since the inception of the program. With this background in mind, the present study was designed to ascertain the health status of (NSP) TB patients after treatment completion and evaluate relapse rate and mortality for the initial block period of five years following implementation of RNTCP-DOTS in Udupi district.

MATERIALS AND METHODS

A retrospective cohort study was conducted in TB unit situated in Udupi taluk of Udupi district. In this district, TB cases are detected at 24 primary health centres where symptomatic patients were screened by examination of two sputum smears for acid-fast bacilli (AFB).

The study population included all the voluntarily consenting new smear positive TB patients registered for treatment in the year 2005, in Udupi TB unit

Patients above 15 yrs of age at the time of receiving treatment and patients declared to have completed treatment or cured following DOTS Category I treatment were included in the study.

All the successfully treated NSP patients for the year 2005 (n=224), fulfilling the eligibility criteria were entitled to be part of the cohort.

METHODOLOGY

Institutional ethical committee clearance was obtained before initiation of the study. (IEC no. 226/2011) All the necessary permissions were obtained to access the records in the District tuberculosis office and to interview study subjects at their residence. The list of new smear-positive TB patients registered in the year 2005 and declared

cured or treatment completed was obtained from TB - unit register in District TB office. Using a structured proforma, the information about TB register number, name, age, sex, address, smear result, treatment details and details regarding the DOTS provider were collected from the treatment cards. The study subjects were listed based on PHC / Treatment Centre. The PHC Medical Officer and DOTS provider were then contacted and requested to assist in locating the subject and to facilitate the interview process. The subject was termed as non-traceable if he was not available during house visit. If the subject was unavailable at the time of first home visit, the subject's current status was enquired from family members and neighbors. The subjects who were reported to be alive and currently residing in the documented address, one more home visit was made to interview the subject. The subject who was unavailable even at the second visit was termed as non-respondent. If the subject was reported to have died during the follow up period, the date and cause of death was determined from the PHC medical officer, Auxiliary Nurse Midwife (ANM), Anganawadi Worker (AWW) or relatives. Personal interviews were conducted with the subjects available at their residence using a semi-structured pre-tested interview schedule translated into the local language. Subjects were recruited into the study after elucidating the objectives of the study, reassuring them regarding confidentiality of the information to be collected and obtaining written informed consent. Two sputum samples of symptomatic subjects were collected and tested for Acid Fast Bacilli (AFB) at the Designated Microscopy Centre (DMC) located at Government District Hospital - Udupi / the nearest DMC to the subject's residence. The report of the sputum smear tested AFB was collected and informed to the subject. The subject with positive sputum smear report for AFB was referred to the nearest PHC for treatment.

Case definitions

The definitions used in the study were as laid down by the World Health Organization (WHO) and RNTCP.⁵

New patients: TB patients who have never had treatment for TB or those who have taken anti-TB drugs for less than one month.

Smear-positive patient: A patient with at least two initial sputum smear examinations (direct smear microscopy) positive for acid-fast bacilli (AFB) or a patient with one sputum examination positive for AFB and radiographic abnormalities consistent with active pulmonary TB as determined by the treating Medical Officer (MO) or a patient with one sputum specimen positive for AFB and culture positive for *M. tuberculosis*.

Cured: Patients who were initially sputum smear-positive, and completed treatment and had negative sputum smears, on at least two occasions, one of which was at the end of treatment.

Treatment completed: A sputum smear positive patient who has completed treatment, with negative smears at the end of Intensive Phase(IP) but none at the end of treatment

Treatment success: The sum of patients who are cured and those who have completed treatment

Relapse: A patient who was declared cured or treatment completed by a physician, but who reported back to the health service and was found to be sputum smear-positive.

Statistical analysis: The data was entered and analyzed using SPSS version 15 (Statistical Package for Social Sciences, South Asia, Bangalore). Results are presented as percentages and proportions. Person-years of observation (PYO) was calculated from the date of cure to date of interview. Recurrence rate was calculated as the number of recurrences per 100 PYO. Chi-square test was applied to ascertain the association between current status of the subjects and socio-demographic variables. p-value < 0.05 was considered to be statistically significant.

RESULTS

Success rate, rates of mortality and loss to follow-up: A total of 549 patients of Tuberculosis were registered for treatment under RNTCP - DOTS in the year 2005 under the Udupi TB Unit. The number of New Sputum Positive (NSP) patients treated

with Category I (Cat I) treatment were 224, among whom the subjects who fulfilled the inclusion criteria of being successfully treated were 177. Therefore, the treatment success rate was 79% among TB patients who underwent Cat I treatment. A total of 174 (98.3%) subjects complied with regular DOTS treatment and the mean (SD) duration of treatment was six months (± 0.513). Of the 177 subjects eligible for the study, 118 were traceable and 59 were non-traceable. Thus a total of 118 subjects were followed up for a median of 5.6 years (IQR: 5.30-5.89) from the date of completion of treatment to the date of interview. The subjects were followed up for a total of 623.67 person years. Among the traceable subjects, 18 (15.2%, i.e. 18 out of 118 subjects) had died during the follow-up period and hence only 100 were available for interview. The major reason for the non-traceability of the subjects, as shown in **Table 1**, was migration. From the information retrieved from the PHC medical officer, none of the 18 deceased individuals included in the study died due to tuberculosis (**Figure 1**).

Table 1: Follow up details of study subjects (n =177)

| Follow up Status | Frequency (%) |
|---|---------------|
| Traceable n = 118, (66.7 %) | |
| No history of TB | 98 (55.4) |
| History of TB | 2 (1.1) |
| Death | 18 (10.2) |
| Non - Traceable n = 59, (33.3 %) | |
| Migrated | 36 (20.3) |
| Inadequate address | 7 (4) |
| Locked house | 16 (9) |
| Total | 177 |

Table 2: Age and gender distribution of the study population

| Age | Male | | | | Female | | | | Total (males + females) | | | |
|--------------|-----------|-----------|---------------|------------|-----------|----------|---------------|-----------|-------------------------|-----------|---------------|------------|
| | Alive* | Dead | Non traceable | Total | Alive* | Dead | Non traceable | Total | Alive* | Dead | Non traceable | Total |
| 15 - 24 | 15 | 0 | 9 | 24 | 5 | 0 | 2 | 7 | 20 | 0 | 11 | 31 |
| 25 - 34 | 18 | 2 | 13 | 33 | 5 | 2 | 5 | 12 | 23 | 4 | 18 | 45 |
| 35 - 44 | 17 | 3 | 5 | 25 | 7 | 0 | 5 | 13 | 24 | 3 | 10 | 38 |
| 45 - 54 | 19 | 3 | 8 | 30 | 3 | 0 | 3 | 6 | 22 | 3 | 11 | 36 |
| 55 - 64 | 6 | 3 | 5 | 14 | 0 | 1 | 2 | 3 | 6 | 4 | 7 | 17 |
| ≥ 65 | 2 | 4 | 0 | 6 | 3 | 0 | 1 | 4 | 5 | 4 | 1 | 10 |
| Total | 77 | 15 | 40 | 132 | 23 | 3 | 18 | 45 | 100 | 18 | 58 | 177 |

* Alive indicate cases interviewed.

Socio demographic characteristics: **Table 2** shows the age and gender distribution of the traceable and non traceable subjects and **table 3** shows the other socio demographic characteristics of the interviewed subjects. Out of the total patients interviewed 77% were males. Majority (67%) of the subjects were between the ages 15 to 44 years. Out of the total subjects 96% were Hindus and approximately two thirds were married (71%). The overall literacy status among the study subjects is 79%

with 71% educated upto the pre university level. Eighty two percent of the study subjects were employed, 33% were unskilled labourers, 41% gainfully occupied and 8% professionals. Socio-economic status as assessed by Modified B G Prasad's Scale (August, 2011) showed that 55% subjects belonged to lower class, 40% to middle class and remaining 5% to upper class.

Table 3: Association of socio-demographic factors according to recurrence of tuberculosis among study subjects

| Variables | Recurrence (n=2) (%) | No recurrence (n=98) (%) |
|------------------------------------|----------------------|--------------------------|
| Age Category | | |
| 15 – 24 | Nil | 20 (20.4) |
| 25 – 34 | Nil | 23 (23.5) |
| 35 – 44 | 1 (50.0) | 23 (23.5) |
| 45 – 54 | 1 (50.0) | 21 (21.4) |
| 55 – 64 | Nil | 6 (6.1) |
| >=65 | Nil | 5 (5.1) |
| Gender | | |
| Male | 2 (100) | 75 (76.5) |
| Female | Nil | 23 (100) |
| Religion | | |
| Hindu | 2 (100) | 94(96) |
| Muslim | Nil | 2 (2) |
| Christian | Nil | 2(2) |
| Current marital status | | |
| Unmarried | Nil | 23 (23.5) |
| Married | 2 (100) | 69(70.4) |
| Widow / Widower | Nil | 4(4.1) |
| Divorce/ Separated | Nil | 2(2) |
| Education | | |
| Illiterate | 1 (50) | 20(20.4) |
| Primary | Nil | 16 (16.3) |
| Higher primary | 1 (50) | 27 (27.6) |
| High school | Nil | 22 (22.4) |
| PUC / Diploma | Nil | 5 (5.1) |
| Degree | Nil | 7 (7.1) |
| PG / PhD | Nil | 1(1.0) |
| Occupation | | |
| Unemployed | 1 (50) | 17 (17.3) |
| Unskilled | 1 (50) | 32 (32.7) |
| Semi-skilled | Nil | 18 (18.4) |
| Skilled | Nil | 7 (7.1) |
| Business | Nil | 5 (5.1) |
| Professional | Nil | 8 (8.2) |
| Student | Nil | 2 (2) |
| Housewife | Nil | 9 (9.2) |
| Family size | | |
| 4 or Below | 1(50) | 40 (40.8) |
| 5 - 7 | 1(50) | 39 (39.8) |
| 8 and above | Nil | 19 (19.4) |
| B G Prasad's Classification | | |
| Upper Class (>4200) | Nil | 5 (5.1) |
| Upper Middle (2100-4199) | 1 (50) | 12 (12.2) |
| Lower Middle (1260-2099) | Nil | 27 (27.6) |
| Upper Lower (630-1259) | Nil | 38 (38.8) |
| Lower (<629) | 1 (50) | 16 (16.3) |

Rate of relapse: As seen in tables 3, out of the 100 interviewed subjects, recurrence of TB in the follow up period was reported among two male patients, both married, one aged 35 years (belonging to the low income group) and the other, 50 years of age (belonging to the upper middle income group). These episodes of TB were re-treated at the PHC / Public health system. Since the total number of years followed up for 118 study subjects was 623.67 person years and the number of recurrences was two, it follows that recurrence per 100 person

year observation (PYO) is $(2/623.67 \times 100) = 0.32$. Thus, the rate of recurrence is 0.32 per 100 PYO.

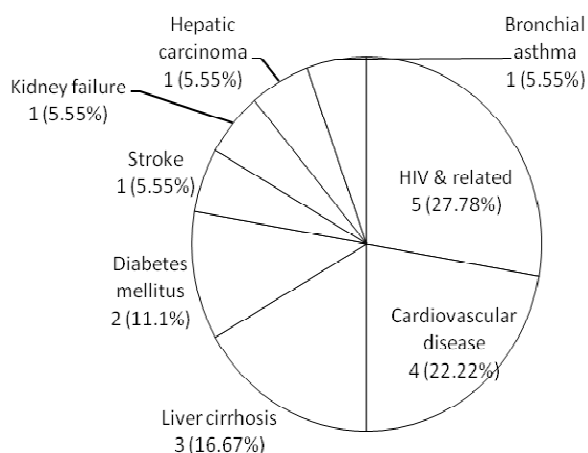


Figure 1: Causes of Mortality among the Traceable Study Subjects

DISCUSSION

This study assessed the profile and health status of NSP-TB patients, five years after treatment completion, who were registered under RNTCP program in the year 2005, that is within six months of launch of RNTCP (July 2004) in the district. In the background of DOTS strategy being newly implemented, a treatment success rate of 79% (compared to 85% at national level) ^{3,6} certainly indicates DOTS to be the right strategy to strengthen the program. Further 98.3% compliance of the subjects to the DOTS regimen, is a major contributing factor to the observed success rate. The high literacy (79%) and employment (82%) rates among the study subjects could also have been responsible for complying with the treatment regimen. Nevertheless, the rate of success of the programme can further be improved by active involvement of all health care providers including private practitioners in the district, for the implementation of the DOTS strategy for tuberculosis control.

A total of 59 (33.3%) subjects included in the study were non-traceable during follow up. Similar observations have been reported in studies in other regions in the country with Prasad R et al ⁷ reporting only 66.7% traceability while Verma SK et al ⁸ report that only 42.8% patients could be traced. These researchers^{7,8} have attributed migration and recording of improper address in the register, as the main reasons for non-traceability of the registered patients, similar to the present study. Other studies have reported the rate of loss to follow-up ranging from 5% to 60%.^{8,9,10,11,12} The high rate of migration could be attributed to the long duration of follow-up after treatment completion. Incorrect addresses may be due to the fact that 55% of the

patients belonged to lower socioeconomic class and hence, do not have permanent residential address. This line of thinking is in tune with earlier research⁸ findings.

The death rate in other Indian follow-up studies ranged from 3.8% to 8.5%^{13,14,15} which was lesser than the present study (15.2%). Although the proportion of deaths was higher, none of the deaths, were attributable to tuberculosis, as per the report of the PHC medical officer. The authors wish to reiterate here that the cause of deaths in all 18 subjects was as recorded by the PHC medical officer and not according to autopsy reports. This could be a limitation of the present study, with respect to ascertainment of the specific cause of death.

The relapse rate was found to be lower in the present study (1.7%) than reported in earlier literature 4.5 - 7.4%^{13,14} and 11.4 %¹⁵ for two years and two-and-half years respectively. The lower relapse rate in the present study even after five years as compared to other shorter duration follow-up studies speaks of the successful implementation of the DOTS program in this district. Out of the two patients with recurrence, one was declared to have been infected with multi drug resistant (MDR) strain for which he was treated with Non-DOTS (ND - 1) regimen for duration of 10 months after which he was declared cured and was found to be symptom free for ten months thereafter. The second patient was retreated at the district hospital.

CONCLUSION

In conclusion, DOTS strategy has yielded good treatment success rates during the initial stages of program implementation. Hence, it is imperative that the DOTS regimen for tuberculosis control needs to be implemented with increased interest and active involvement by all health care service providers including private practitioners. It is recommended that further studies should be conducted in second block of five years period (2010 - 15) of implementation to find out the success rates and sustainability of the implementation of the DOTS strategy compared to the 1st block period (2005-10).

Limitation: One third of the subjects being non-traceable during follow-up period has been a limiting factor in the study. Secondly, the cause of deaths in all 18 subjects were recorded as mentioned by the PHC medical officer and not according to autopsy reports. In addition, recall bias due to the long duration of follow up cannot be ruled out.

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