Short communication

STATUS OF SMEAR-POSITIVE TB PATIENTS AT 2-3 YEARS AFTER INITIATION OF TREATMENT UNDER A DOTS PROGRAMME

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Summary
***Objective*:** To describe the status of cases 2-3 years after the initiation of treatment under DOTS.
***Setting*:** After DOTS implementation in Tiruvallur district, south India, we followed up a cohort of smear-positive TB patients registered during 2002-03 after initiation of treatment.
***Results*:** The overall mortality rate was 15.0% and among the remaining 18.6% had active disease. In multivariate analysis, a higher mortality rate was independently associated with age, sex, occupation, treatment outcome and initial body weight of patients.
***Conclusion*:** The mortality and morbidity rates are still high during follow-up and needs to be curtailed by addressing these issues effectively in TB control programme. **[*Indian J Tuberc 2007; 54:199-203*]**

***Key words*:** DOTS, Follow-up, Mortality, Smear-positive

INTRODUCTION

The Directly Observed Treatment- Short Course (DOTS) strategy, with the objectives of curing at least 85% new smear-positive cases and detecting a minimum of 70% of these cases has been beneficial and successful in reducing the death rates and increasing the successful treatment outcomes[1] (cure and treatment completion). It reduces the chances of default, failure and relapses and prevents emergence of multi-drug resistant tuberculosis (MDRTB). Tuberculosis Research Centre (TRC) had monitored the DOTS programme in one TB unit (TU) of Tiruvallur district, south India for a period of 5 years since its implementation in 1999 and undertaken different operational studies and generated valuable data on various components. We have not looked into the long term status of cases treated under a DOTS programme. This paper describes the status of cases 2-3 years after the initiation of treatment under DOTS in the same area and describes the ways and means of reducing the mortality and morbidity.

METHODOLOGY

The study area is semi-urban with a population of 580,000 having 17 governmental health care facilities, including 7 designated microscopy centers for sputum examination. Subjects attending these health facilities with a history of chest symptoms or cough for 3 weeks or more were screened for TB by sputum smear microscopy by Ziehl-Neelsen method[2]. Those diagnosed to have TB were categorized, treated and monitored according to the RNTCP guidelines.[3] Smear-positive TB patients registered for treatment during the year 2002 and 2003 formed the study population. Those who were in 2002 and declared successfully treated, defaulted or failed were followed-up three years after the initiation of treatment and those registered in 2003 were followed–up after two years. Two sputum specimens were collected from those who were available at the time of the visit by a health worker at their residence. These specimens were transported to the TRC laboratory and processed for smear, culture and drug susceptibility tests. A patient

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was considered positive if he became (i) smear-positive on two specimens or (ii) one smear-positive and culture-positive on either of the specimens or (iii) one culture or both cultures positive.

ANALYSIS AND RESULTS

The data were computerized and further edited for any discrepancy and missing information. The Chi-square test was used for testing the difference in the proportions. Univariate analysis was performed to find the distribution of factors among patients died during the follow-up. Odds ratio (OR) and 95% confidence intervals (95% CI) were calculated. In multivariate analysis, significant factors were included to find independent association of factors with mortality rates adjusting for confounding factors. Adjusted Odds Ratios (AOR) were also obtained. Statistical significance was set at $P \leq 0.05$.

A total of 1171 smear-positive cases were registered for treatment during the period 2002-2003. Of these, 880 were new smear-positive cases (Category I), 255 previously treated smear-positive cases (Category II) and the remaining 36 cases were treated under non-DOTS regimens. Among the 36 treated under non-DOTS, three were declared 'cured', twenty seven defaulted, four expired, and two failed. Fifty-eight patients expired during treatment period. Thus, there were 1113 cases eligible for follow-up. However, 25 cases for follow-up were missed due to some unavoidable factors. Of the remaining 1088 cases followed up, 148 expired, 54 migrated and 46 could not be traced despite three attempts. Sputum samples were collected from the remaining 840 cases. The overall mortality rate was 15.0% (148 of 988; annually 6.1%) and among the remaining 18.6% (156 of 840) had active disease. The mortality was 11.3% (87 of 768) for category I patients compared to 25.7% (53 of 206) for category II patients The overall mortality was higher among defaulted (42.0%; 74 of 176) and failed (34.4%; 22 of 64) patients compared to patients who have successfully completed the treatment (6.0%; 44 of 734). Category II patients had more active cases (29.4%; 45 of 153) than Category I patients (15.7%; 107 of 681) (Table 1).

The risk factors for a higher mortality among all smear-positive cases followed-up are shown in Table 2. In univariate analysis, mortality was significantly higher among patients aged > 40 years than among patients < 40 years (22% vs 8%); Similarly, a higher proportion of mortality was significantly associated with male sex, unemployment, smoking, drinking, resistance to isoniazid (H)/ rifampicin (R) and in both RH, previous history

Table 1: Status at follow-up by category and outcome of former treatment outcome of patients treated under a DOTS programme in a district, south India

	Category I				Category II			
Outcome	Expired (%)	Pos*	Neg^{+}	Total	Expired (%)	Pos	Neg	Total
Cured	39(6.0)	75	532	646	5(5.7)	19	64	88
Defaulted	32(43.8)	14	27	73	42(40.8)	23	38	103
Failed	16(32.7)	18	15	49	6(40.0)	3	6	15
Total	87(11.3)	107	574	768	53(25.7)	45	108	206

* Positive by smear and/or culture, + Negative by smear and culture
Note: 14 cases put on non-DOTS treatment regimens were excluded

of anti-TB treatment, default/failure, non-conversion, first action at government center and having body weight ≤ 40 kg. In multivariate analysis, a higher mortality rate was independently associated with age, sex, occupation, treatment outcome and weight of patients.

A higher proportion of active disease was independently associated patient's former treatment outcome, resistance and smoking (data not tabulated).

Table 2: Risk factors for mortality among smear-positive patients 2-3 years after the initiation of treatment under a DOTS programme in a rural district, south India

Risk factors		No. of patients	Died (%)	OR (90% CI)	AOR (90% CI)
Age	≤ 40 yrs	512	42(8)	3.2 (2.2 – 4.8)	2.2 (1.3 – 3.7)
	> 40 yrs	476	106(22)		
Sex	Male	728	129(18)	2.7 (1.6 – 4.7)	2.8 (1.4 – 5.8)
	Female	260	19(7)		
Education	Illiterate	398	64(16)		
	Literate	552	64(12)	1.5 (1.0 – 2.2)	
Occupation	Un-employed	363	60(16)	1.5 (1.0 – 2.2)	2.0 (1.2 – 3.3)
	Employed	588	69(12)		
Smoking	Yes	445	85(19)	2.5 (1.7 – 3.7)	
	No	506	44(9)		
Drinking	Yes	366	64(18)	1.7 (1.2 – 2.5)	
	No	585	65(11)		
Sensitive on admission	Sensitive	828	101(12)		
	Res. H/R/HR	122	34(28)	2.8 (1.7 – 4.4)	
Patients	New	775	93(12)		
	Old	213	55(26)	2.6 (1.7 – 3.8)	
Outcome	Success	734	44(6)		
	Default/Failure	254	104(41)	10.9 (7.2 – 16.4)	10.5 (6.4 – 17.1)
Conversion at the end of IP	Yes	825	78(10)		
	No	163	70(43)	7.2 (4.8 – 10.8)	
First action	Govt.	519	82(16)	1.5 (1.0 – 2.3)	
	Private/Others	432	47(11)		
Weight on admission	≤ 40kg.	433	81(19)	2.1 (1.4 – 3.2)	2.8 (1.7 – 4.6)
	>40Kg.	452	44(10)		

The number of patients is less than 988 due to non-availability of all patients at the time of interview within a week after treatment started.

DISCUSSION

The main finding of this study is that among those smear-positive cases declared successfully treated, defaulted and failed; after 2-3 years of initiation of treatment, 15% had died and among the remaining 19% were bacteriologically positive excreting TB bacilli in the community. An earlier study[4] from the same area reported a 12% relapse after a two-year follow-up of cured new smear-positive patients (category I). The present study findings were for those cured, defaulted and failed patients followed up for a period of 2-3 years after starting the treatment. In the present study also the relapse rate was estimated to be 12% (75 of 607) among new smear-positive cases (category I) declared 'cured'. When the defaulted and failed cases were included the proportion of the number of active cases increased to 16% (107 of 681). The corresponding figures for category II cases were 23% (19 of 83) and 29% (45 of 153) respectively (Table 1).

In a study[5] (1988-89) from North Arcot district in Tamil Nadu during the SCC period before implementation of DOTS, the overall mortality rate was reported to be 28% and of the remaining 31% had active TB (not all patients had SCC). In our study, we have observed less mortality and active TB. This is because of an effective and successful TB control program like DOTS. Still, the mortality and morbidity rate was high and it is more among default and failure cases compared to cured, including treatment completed cases. Among the 148 patients died, we could not ascertain whether they died with positivity after treatment or not. The proportion of active cases would have been much higher had we included these cases. A study[6] on risk factors associated with default, failure and death, higher death rates were independently associated with body weight and previous history of treatment. We can reduce mortality by preventing the default and returning defaulters to treatment. It may be noted that the overall default rate is high (9.5%; 73/768) but has come down considerably over the time-periods. This can be achieved by making DOTS more convenient to patients. Male patients and those above 40 years should be motivated for regular treatment. For under weight patients, nutritional supplementation should be explored. In a recent follow-up study[7] in Chennai city, the mortality rate of patients treated under DOTS was 60/1000 person years and the excess mortality rate was six times more than the general population. A study is warranted to assess whether there is any primary hidden failures were present at the time of classifying the patients as completed treatment and any unconfirmed deaths among the defaulters.

In conclusion, the mortality rate and those who had active TB was high among smear-positive cases followed up at 2-3 years after the initiation of treatment. These rates, still, need to be reduced by addressing the issues effectively in TB control programme.

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