



Treatment Outcome of Smear Positive Pulmonary Tuberculosis Patient in Ajmer -Retrospective Assessment after 5 Years

Authors

Jacob George P¹, Rakesh C. Gupta², Neeraj Gupta³, Ramakant Dixit⁴, Ankur Gupta⁵,
Amilu Elsa Varghese⁶

¹Senior Resident, Dept of Anesthesia Critical Care and Pain, Tata Memorial Hospital, Mumbai
Email: hipulian@yahoo.com, 9496465619

²Professor and Former HOD of Respiratory Medicine, JLN Medical College Ajmer

³Professor and HOD of Respiratory Medicine, JLN medical College Ajmer

⁴Associate Professor, Dept of Respiratory Medicine, JLN Medical College Ajmer

⁵Senior Medical Officer, Dots Plus, Dept of Respiratory, Medicine JLN Medical College, Ajmer

⁶Former Senior Resident, Dept of Radiodiagnosis, Govt Medical College

Corresponding Author

Amilu Elsa Varghese

Former Senior Resident, Dept of Radiodiagnosis, Govt Medical College, Kottayam

Abstract

Background: Pulmonary Tuberculosis seen in one third of patient worldwide. Estimated incidence of the disease in India is 1.96 million new cases annually of which 0.8 million are new smear positive. Revised National Tuberculosis Control Program plays an important role in managing Tuberculosis cases in India. However there is an inherent weakness in the system so that the patients completing treatment are not being followed up. This study was carried out to follow up the smear positive patients who had taken CAT II DOTS under RNTCP five years back and assess the, frequency of relapse, ultimate fate of patients, default rate and factors associated with default

Materials and Methods: A retrospective study, conducted in Department of Pulmonary Medicine in J.L.N Medical college Ajmer in which 161 patients registered under category II between January 2005 – January 2006 were included.

Results: Out of the total 161 patients, only 102 patients (63.35%) were traced after 5 years. Among the traced patients we found that 34% of patients were asymptomatic, 18% patients were suffering from various non tubercular respiratory ailments or sequela of TB like obstructive airway disease, Post TB bronchiectasis, episodes of hemoptysis, recurrent respiratory tract infections etc. The mortality rate was 49% at the end of 5 years.

Conclusion: Treatment after default was the most common indication (77.01%) for starting Cat II DOTS in Ajmer TU in 2005. Ajmer TU recorded a higher default rate (27.95%) and lower cure rate (60.86%) compared to national figures for the year 2005.

Introduction

Nearly one-third of the global population is infected with Mycobacterium Tuberculosis¹. Global estimates of the burden of Tuberculosis

related disease and death for 2008 estimated 9.4 million incident cases of TB, with 1.3 million deaths².

Estimated incidence of the disease in India is 1.96 million new cases annually of which 0.8 million are new smear positive. It is estimated that 75 new smear positive PTB cases/1 lakh populations per year are present in India³ This disease is a giant killer with an estimated mortality 330,000 deaths due to TB each year, over 1000 deaths a day and 2 deaths every 3 minutes. As per WHO records of 2007, India records the highest number of deaths due to tuberculosis, followed by China.

The Revised National Tuberculosis Control Program (RNTCP), based on the internationally recommended DOTS strategy. Presently Indian DOTS is the second largest public health program of the world and more than 86% of our country population has been covered under this program⁴. Under RNTCP patients are categorized into 2 categories on the basis of two determinants (sputum smear status, severity of TB disease and history of previous treatment of TB) before patient is put on DOTS.

CAT I - New Smear Positive, New Smear Negatives, New Extra Pulmonary, New Others.

CAT II – Smear positive relapse, Smear positive failure, Smear positive treatment after default, others.

Relapse - a TB patient who was declared cured or treatment completed by a physician in the past, but who reports back to the health service and is now found to be sputum smear-positive.

Treatment after failure - a TB patient who is smear-positive at 5 months or more after starting treatment or a initial smear negative TB patient who turns out to be smear positive.

Treatment after default (TAD)- a TB patient who received anti-tuberculosis treatment for one month or more from any source and returns to treatment after having defaulted, i.e., not taken anti-TB drugs consecutively for two months or more, and is found to be sputum smear-positive

Even though RNTCP uses an internationally accepted DOTS regimen and consistently achieves the twin objectives of 85% case detection and 70 % sputum conversion, many health care workers, especially those in private sectors views the

program with sceptism. To obtain optimal cooperation from all levels of health care, it is necessary to evaluate the programme periodically and retrospectively. The present health system inherently lacks facility for routine follow up and periodic assessment of patients cured under RNTCP. Hence we conducted this study to assess the ultimate fate of patients managed under Category II of RNTCP,

Study was carried out to follow up the smear positive patients who had taken CAT II DOTS under RNTCP five years back and assess the Frequency of relapse, Ultimate fate of patients, Default rate and factors associated with Default, Incidence of M.D.R cases already diagnosed, in sputum positive cases treated with CAT II regimen and Associated co morbidities

Subjects and Methods

All consecutively diagnosed sputum positive Pulmonary Tuberculosis cases registered under Category-II at local Tuberculosis Unit (TU) between the periods of January 2005 to January 2006 were included in this study. There are 19 DOTS centers in our place and a total of 161 patients were selected.

All forms of extra pulmonary tuberculosis, pulmonary tuberculosis with severe form of extra-pulmonary TB patients was excluded from this study, because the mortality was expected to be higher and may bias the result

Methodology

Out of 161 patients 102 were traced and a retrospective analysis of record was done to assess various immediate outcomes. The regularity of treatment was assessed with treatment cards. Home visit was conducted in each case and details of the socio – economic back ground, patients living conditions were personally analysed. Detailed interaction was undertaken with each patient, to understand the problems faced by them during and after the treatment

Symptomatic patients were motivated for a repeat chest X ray and sputum examination under

RNTCP. Details of any other/associated medical or surgical illnesses, nature and duration of the re-treatment taken, appearance of symptoms of relapse, sputum status and other investigations done, culture & sensitivity reports if available, history of contact and spread, occupational details, addiction habits, educational and socio-economic status, history of OPD visit & hospitalization and detailed notes of death during 5 years was

recorded. A Verbal autopsy tool, was used in all the death cases to find out the cause of death as accurately as possible. We selected – WHO Study on Global Ageing and Adult Health 2007 as our verbal autopsy tool, as it is internationally accepted

The results obtained were tabulated and chi square test was applied for the testing of significance of values.

Results

Table 1: Input for smear positive re- treatment cases in our study.

Type of patient	Our study (%)	India(%)	Rajasthan (2009)
Relapse	16.14	45.55	53.25
TAD	77.01	43.73	39.41
Failure	6.83	10.75	7.33
Total	99.99%(161)	99.99(165283)	

According to our study, the most common indication for starting category II in smear positive patients was treatment after default. The

relapse cases were significantly lower than national figures and TAD cases were significantly higher than national figures ($p < 0.001$).

Table 2: Comparing Outcome of smear positive retreatment cases in our study Rajasthan and India for the year of 2005

Outcome	Our study	Rajasthan	India
Cured	98(60.86%)	14916.29(76.9%)	113549(68.7%)
Failure	7(4.34%)	718(3.7%)	9421(5.7%)
Defaulted	45(27.95%)	2482.81(12.8%)	27768(16.8%)
Died	8(4.96%)	1106(5.7%)	1333(7.5%)
Transferred out	3(1.86%)	194 (1.0%)	1.2%

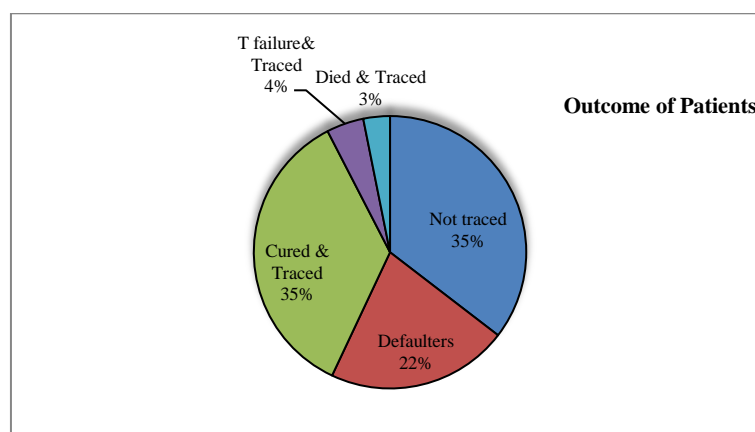


Figure1- showing the fate of sputum positive patients managed under category II of RNTCP in our study at the end of 5 years, in 2010.

Out of the total 161 patients, we could trace out only 102 patients at the end of five years (63.35%). The remaining 56 patients could not be located either because of incomplete address, migration or change in residential address. Three

patients were transferred out to other TU for further management and could not be contacted. Among the 102 patients traced, 56 were declared cured, 34 as defaulters, 7 treatment failures and 5 died on treatment.

Table 3: Treatment outcome and its influence on patient tracing

Sl No	Treatment outcome	Traced
1.	Cured n= 98	56
2.	Defaulters n = 45	34
3.	Failure n= 7	7
4.	Died n= 8	5
5.	Transferred Out n=3	-

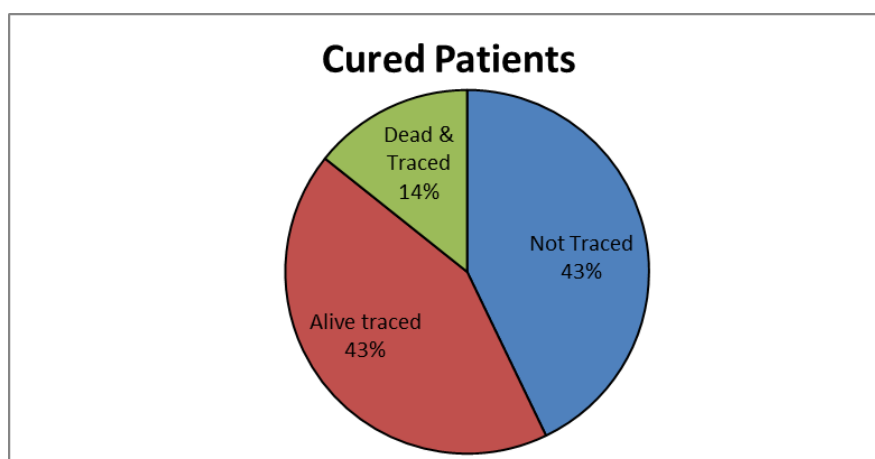
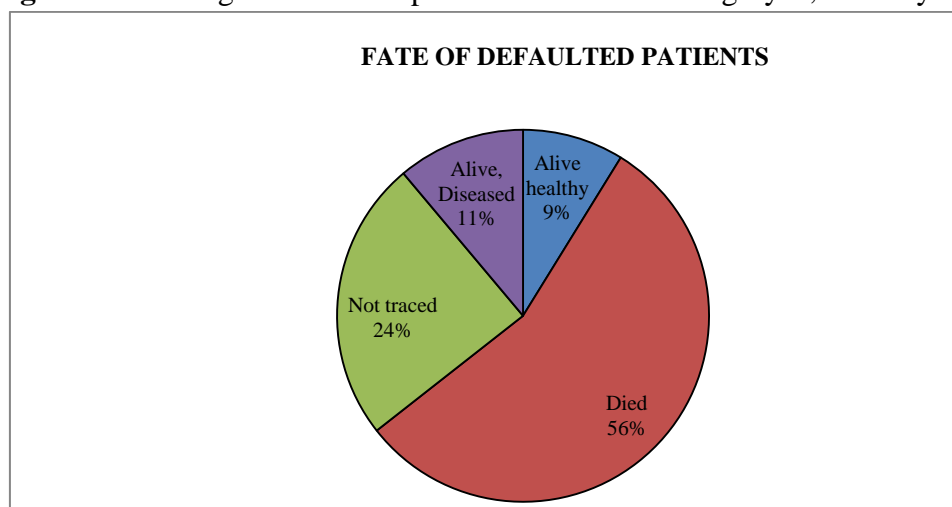
57.14% of the cured, 75.55% of the defaulted, 100% of treatment failure and 62.5 % of patients who died on treatment could be traced.

Table 4: Fate of sputum positive patients managed under category II of RNTCP in our study at the end of 5 years

Fate of traced patients at the end of 5 years	Cured	Defaulted	Treatment failure	Died on treatment	Total
Asymptomatic	30(29.41)	4(3.9)	1(0.9)	-	35(34.31%)
Symptomatic	12(11.76)	5(4.9)	1(0.9)	-	18(17.64)
Dead	14(13.72)	25(24.50)	5(4.9)	5(4.9)	49(48.03)

At the end of 5 years, we found that only 34% of patients were asymptomatic. 18% patients were suffering from various non tubercular respiratory ailments or sequela of TB like obstructive airway disease, Post TB bronchiectasis, episodes of

hemoptysis, recurrent respiratory tract infections etc. The mortality rate was 49% at the end of 5 years. Out of the 35 asymptomatic patients, 30 had attained a microbiological cure, while 4 defaulted and 1 patient failed on treatment.

**Figure 2-** showing fate of cured patients in RNTCP Category II, after 5 years**Figure 3:** Fate of treatment defaulters after 5 years

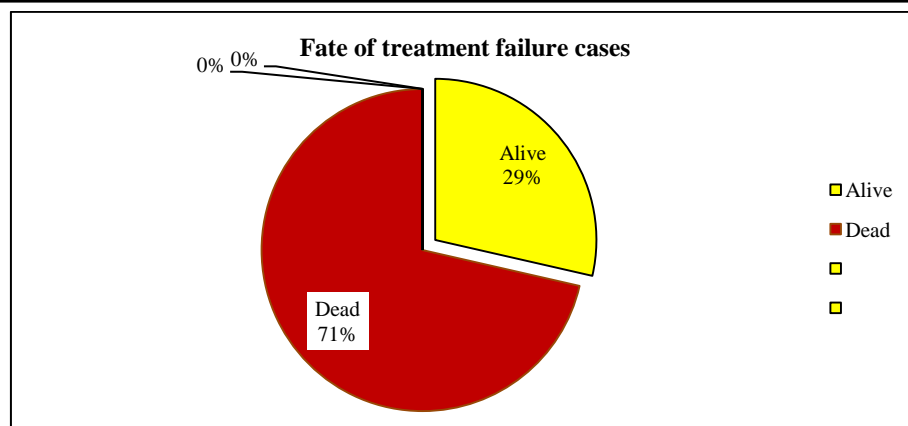


Figure 4- Fate of treatment failure cases after 5 years

Discussion

Analysis of the type of patients in Category II in our study suggests, 77% of cases were treatment after default, significantly higher than national figures. This was similar to a study conducted in Rajasthan itself by Sisodia et al in 2003⁵

According to our study, the most common indication for starting category II in smear positive patients was treatment after default. Compared with a study conducted by Mukherjee et al⁶ in West Bengal, found that relapse was the most common cause for starting category II retreatment in West Bengal from 1999 - 2005. The disparity is attributed to the difference in the availability of doctors of private sector in rural West Bengal compared to urban population in our study.

Menzis et al⁷ in 1996 found that residents of affluent neighbourhood were less likely to report for treatment. Our study population being in an urban area have jobs with a nature demanding frequent travel, thereby making DOTS a difficult option.

All these reasons cumulatively may be the cause for a high percentage of TAD patients in our study.

Wrong categorization of patients in DOTS may occur as noted by Sisodia et al⁵ also. They found out that in 2003, 4 of the 200 patients studied were wrongly categorized as defaulters and 1 patient as relapse and started on category II.

Our study showed that as much as 40% patients did not have any documented evidence of

previous ATT. This may be due to wrong categorization of patients or merely a fact that patients were unaware and not counseled of the nature of disease.

Our study recorded a success rate of 61% which was significantly low compared to national and state standards. The default rate in our study among the sputum positive re treatment cases was about 28% which is also significantly high. There is an inherent weakness in the system to follow up the defaulters.

Conclusion

161 patients registered under category II between January 2005 – January 2006 were included in the study.

Treatment after default was the most common indication (77.01%) for starting Cat II DOTS in our study.

Compared to national figures for the year 2005, our study recorded a higher default rate (27.95%) and lower cure rate (60.86%)

Only 63.35 % out of the total 161 smear positive patients who took treatment under CAT II could be traced out.

Only 52 % of patients who were traced are alive, the remaining 48% being dead due to reasons primarily or secondarily related to tuberculosis.

34 % of patients were cured of disease and leading a healthy life while 18% of patients were suffering from other co morbidities like COPD

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