International Journal of Community Medicine and Public Health
Sharma A et al. Int J Community Med Public Health. 2016 Aug;3(8):2129-2132
http://www.ijcmph.com
pISSN 2394-6032 | eISSN 2394-6040

DOI: http://dx.doi.org/10.18203/2394-6040.ijcmph20162558

Research Article

Treatment outcome of new smear positive patients of pulmonary tuberculosis treated under directly observed treatment, short-course in a rural tertiary care hospital of a hilly area

Aradhna Sharma[1]*, Dinesh Kansal[1], Kiran Katoch[2], Parveen Kumar Sharma[1], Rekha Bansal[3], Tarun Sharma[4]

[1]Department of Pharmacology, Dr. RPGMC Kangra at Tanda, Himachal Pradesh, India
[2]National JALMA Institute of leprosy and other mycobacterial diseases, Agra, Uttar Pradesh, India
[3]Department of Pulmonary Medicine, Dr. RPGMC Kangra at Tanda, Himachal Pradesh, India
[4]Department of Medicine, Dr. RPGMC Kangra at Tanda, Himachal Pradesh, India

Received: 07 June 2016
Accepted: 01 July 2016

***Correspondence:**
Dr. Aradhna Sharma,
E-mail: draradhnasharma@gmail.com

ABSTRACT

Background: Tuberculosis is one of the world's most common causes of morbidity and mortality. The directly observed treatment, short-course (DOTS) Strategy aims to improve patient adherence to treatment and thereby prevents development of drug resistance. Aims and Objectives: To study the treatment outcome in new smear positive patients of pulmonary tuberculosis treated under DOTS at DR. RPGMC Kangra at Tanda, H.P.
Methods: A prospective observational study was conducted over duration of seven months in Dr. RPGMC Kangra at Tanda, Himachal Pradesh, India. A total of 130 new smear positive (NSP) patients of pulmonary tuberculosis (PTB) were enrolled during study period after taking informed consent. Patients were started on category I and were followed till the completion of DOTS. Treatment outcomes were recorded as per RNTCP guidelines.
Results: Out of total 130 patients, 109 (83.8%) patients were cured, 14(10.7%) patients died, 2 (1.6%) patients treatment completed, 2(1.6%) patients defaulted, 2 (1.6%) patients were treatment failure and in 1(0.7%) patient treatment regime was modified due to severe hypersensitivity reaction with HRZE. He was put on HES for one year. The mean weight ±SD was 44.5±3.53 kg at the time of start of treatment which increased to mean of 50.6±2.97 kg at the end of treatment. There was an average increase of 6.08±1.12 kg weight at the end of treatment. This was statistically significant and was evenly distributed in all age groups.
Conclusions: The high cure rate and less default rate ensures that the DOTS therapy is highly effective and safe and also the DOTS program is running successfully in this rural hilly area. The increase in weight at the end of treatment was found to be strongly associated with favourable treatment outcome ($p<0.05$). And also furthermore it may be concluded that increased weight can also be included as one of the criteria for the favourable treatment outcome.

Keywords: Pulmonary tuberculosis, DOTS, Weight gain

INTRODUCTION

Tuberculosis (TB) is the second most common infectious disease caused by *Mycobacterium tuberculosis* (Koch bacillus).[1] TB is a worldwide major public health problem and also one of the important cause of morbidity and mortality.[2] In 2013, of the estimated global annual incidence of 9 million TB cases, 2.1 million were estimated to have occurred in India.[3] Smear-positive

pulmonary TB (PTB) constitutes 34% of new TB cases and is most likely a source of TB transmission in the community[4]. A case of untreated smear-positive TB can infect up to 15 people annually and more than 20 people during the natural course of untreated disease.[5,6]

In Himachal Pradesh, TB is quite wide spread among the low socio-economic classes.[7] Himachal has the annualized risk of infection as 1.9% as against that of 1.0% of India.[8] TB continues to be a major public health problem for India, Himachal Pradesh and Kangra. Tuberculosis program in India till 1993 had short course chemotherapy (SCC) regimen, given under unsupervised conditions and the performance of program in terms of success rate was poor.[9]

The Revised National Tuberculosis Control Program (RNTCP), based on the internationally approved Directly Observed Treatment Short course (DOTS) Strategy was started in1995. This was easier and cost effective[10]. Assessment of treatment outcome of newly diagnosed smear positive pulmonary tuberculosis (PTB) patients is used as a major indicator to gauge the effectiveness of national tuberculosis program.

The national cure rate of 88% was documented by RNTCP in 2012 for the new smear positive patients of pulmonary TB at the end of the treatment. In Himachal Pradesh, cure rate documented by RNTCP in 2012 was 87.6%.[11] The DOTS Strategy aims to improve patient adherence to treatment and thereby prevents development of drug resistance.

Despite of high DOTS regionwise coverage and the progress made in TB control in India and Himachal Pradesh, the treatment outcome of TB patients has not been assessed so far. So the present study was carried out in this hilly region to evaluate the treatment outcome of PTB patients treated under DOTS.

METHODS

Study type: A prospective observational study

Study site: Dr. Rajendra Prasad Government Medical College and Hospital Tanda, District Kangra HP

Study duration: Seven months (1stApril, 2012 to 31stOctober, 2012)

Ethical approval: The protocol was approved by Scientific Advisory cum Protocol Review Committee and Institutional Ethics Committee of the Institute.

Inclusion criteria

All the patients of age >12 years of either sex with new smear positive pulmonary tuberculosis.

Exclusion criteria

Patients with HIV positive serology and with renal and liver disease.

Patient enrollment

All the new smear positive (NSP) patients of pulmonary tuberculosis (PTB) diagnosed at the department of pulmonary medicine and consented to participate, were enrolled in the study and were followed till the completion of DOTS therapy. This includes a study size of 130 patients. The study participants were explained about the study in their local language and a written informed consent is obtained before enrollment in the study.

Treatment analysis

The first dose of DOTS was provided to the patients in our DOTS centre. The patient was referred to the nearest TU (treatment unit) and took treatment with the help of RNTCP DOTS provider. In the initial Intensive Phase (IP) DOTS was administered {H (600 mg), R (450 mg) (patients who weighed 60 Kg or more at the start of treatment received an extra 150 mg), E (1200 mg) and Z (1500mg)}, and was given under direct observation thrice a week on alternate days for 2 months (24 doses).Sputum smears were tested at the end of IP and patients who were still sputum smear positive were continued on the same IP for a further 12 doses.

On attaining smear negativity, these patients were administered DOTS as per Continuation Phase (CP), as per RNTCP guidelines. In this phase patients received H (600mg) and R (450 mg) thrice a week for 4 months (54 doses). During this phase the first dose of every week was administered under direct supervision and the following 2 doses of the week, was given for self-administration. Each week the empty DOTS foils were examined to ensure intake of drugs.

Sputum examination for AFB was done at the completion of 4th and 6th months of treatment as per RNTCP guidelines. In patients in whom sputum smear was positive at the end of 2 months of the therapy and the IP was continued for another one month and smear examination was done at the completion of 3rd, 5th and 7th months of treatment.

At the end of six/seven months of treatment**,** treatment outcomes were documented as per RNTCP Guidelines[12].

RESULTS

Out of the total 130 patients 99 were males and 31 were females. The male: female ratio was 3:1.The mean age ± SD of patients was 45±15.75 years. The mean age ± SD of males was 47.6±15.2 years and 36.8±14.7 years in females.

Table 1: Treatment outcome of new smear positive patients treated under dots (n=130).

Outcome	Number of patients	Percentage
Cured	109	83.8
Died	14	10.7
Treatment Completed	2	1.6
Defaulted	2	1.6
Treatment Failure	2	1.6
Treatment modified	1	0.7
Total	**130**	**100**

Out of total 130 patients, 109 (83.8%) patients were cured, 14 (10.7%) patients died, 2 (1.6%) patients treatment completed, 2 (1.6%) patients defaulted, 2 (1.6%) patients were treatment failure and in 1 (0.7%) patient treatment regime was modified due to severe hypersensitivity reaction with HRZE. He was put on HES for one year (Table 1).

The mean weight±SD of the 130 enrolled patients was 44.5±3.53 Kg at the time of start of treatment which increased to mean of 50.6±2.97 Kg at the end of treatment. There was an average increase of 6.08±1.12 Kg weight at the end of treatment. This was statistically significant and was evenly distributed in all age groups (Table 2).

Table 2: Increase in mean weight in patients of new smear positive PTB treated under dots (n=130).

Age in years	Mean weight±SD at the start of treatment	Mean weight± SD at the end of treatment	Difference	p value
<20	38.5±8.9	44.8±7.5	6.3±2.9	0.004*
21-30	42±9.3	50.3±9.0	8.3±2.3	0.000*
31-40	47.2±5.4	52.9±6.0	5.7±2.1	0.000*
41-50	46.7±6.3	51.6±5.8	4.9±2.1	0.000*
51-60	48.9±7.2	54.1±6.9	5.2±2.0	0.000*
61-70	45±8.6	50.6±6.8	5.6±2.4	0.000*
>70	43.4±5.1	49.8±5.1	6.4±2.3	0.001*
Average	**44.5±3.5**	**50.6±2.9**	**6.08±1.12**	

*Significant.

DISCUSSION

The outcome of DOTS not only depends upon the high cure rate but also upon the lesser default and failure rate.

The cure rate in our study was 83.8%. Cure rates in male and female were 82.8% and 87.2% respectively. Though, it was less as compared to the documented cure rate by RNTCP 2012 in India (88%) and 87.6% in Himachal Pradesh.[11] Various studies conducted in different parts of India during 2003 to 2011 the cure rates varies from 77.1% to 85% which are in range as occurred in our study.[13,14,15] In another surveillance data analysis of RNTCP of Kangra H.P, during 2001-2005 , the cure rate was 88-91%. The lesser cure rate in our present study in 2012 could be attributed to the fact that the number of deaths was high in our patient population because of advanced disease at the time of diagnosis. 14 (10.7%) patients died during the treatment due to massive disease and/or due to the presence of other associated illnesses. 11 deaths occurred within the first two months of start of therapy, 3 deaths occurred between 2-4 months of therapy and 1 death occurred after 4th month of therapy. In patients who died after 2nd month of treatment, the cause of death was acute respiratory failure in three patients and massive hemoptysis in one patient. Therefore it can be emphasized that despite of higher literacy rate in Himachal Pradesh as well as Kangra district patient approachs the medical services quite late.

The default rate was less in our study (1.6%) as compared to RNTCP 11 (6%) and other studies conducted conducted in India.[13,14]

2 (1.6%) patients had smear positive sputum at the end of five months that is failure. Failure rate also was lesser or similar as documented in RNTCP and other studies.[13,14] The mean weight ±SD of the 130 enrolled patients was 44.5±3.5 kg at the time of start of treatment which increased to a mean of 50.6±2.9 kg at the end of treatment. There was a significant ($p<0.05$) increase in mean weight of 6.08±1.1 kg from the start of treatment to the end of treatment which was evenly distributed in all decades of age. In the study by Chadha et al there was an average of 2.2 Kg increase in weight at the end of treatment.[13] This increase in weight was found to be strongly associated with favorable treatment outcome.

CONCLUSION

The significance of treatment outcome monitoring in new smear positive pulmonary tuberculosis patients needs to

be further stressed. Doctors, public health experts, and policy makers should be convinced for standardized approach to monitor treatment outcome so as to reduce the incidence of tuberculosis. One of the important finding was despite of lesser default rate, and failure rate, there was a significant increase in weight at the end of therapy. So this increase in weight can be considered as an important marker for a favorable treatment outcome. A limitation of the study was like this; This observational study was a centre based study therefore the patient number was limited. There is a need that such studies should be carried out regularly in different parts of the country. There is a need that such studies should be carried out regularly in different parts of the country so as the performance of the national program is evaluated regularly.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: Institutional Ethics Committee of Dr. RPGMC Kangra at Tanda (No.HFW-DRPGMC/ Ethics/2012/11-12)

REFERENCES

1. Dubos R, Dubos J. The White Plague, Tuberculosis, Man and Society. London: Victor Gollancz; 1953.
2. Global Tuberculosis Control. World Health Organization Report; 2011. Available at: http://www.who.int/tb/publications/global_report.
3. Central TB Division, DGHS, Ministry of Health and Family Welfare, Government of India. RNTCP Annual Status Report, 2015. Available from URL: http://www.tbcindia.gov.in/index1.php?lang= 1& level=1&sublinkid=4160&lid=2807.
4. WHO/IUATLD.Global Project on Anti-tuberculosis Drug Resistance Surveillance, Anti-tuberculosis drug resistance in the World. Report No.4. Geneva, Switzerland.2012.
5. Esther SN, Godfrey SM, Eliud RW, Odd M. Delay in tuberculosis case detection in Pwani region, Tanzania: a cross sectional study. BMC Health Serv Res. 2009;9:196.
6. Mohamed GF, Jens HR, Tore WS, Randi SH, Gunnar B. Patient and health care system delays in the start of tuberculosis treatment in Norway. BMC Infect Dis. 2006;6:33.
7. Gupta SN, Gupta N, Gupta S. Surveillance data analysis of revised national tuberculosis control program of Kangra, Himachal Pradesh. J Fam Med Primary Care. 2013;2:250-5.
8. Global Tuberculosis control, Surveillance, Planning and Financing, WHO: Report 2004. Available at: http://www.who.int/tb/publications/global_report/2004/contents.pdf.
9. Sharma SK, Mohan A. Multidrug resistant tuberculosis. Indian J Med Res. 2004;120:354-76.
10. Khatri GR, Freidan TR. The status and prospects of tuberculosis control in India. Int J Tuberc lung Dis. 2000;43:193-200.
11. Govt. of India. TB India 2012, RNTCP Status Report, Central TB Division, Directorate General of Health Services, Ministry of Health and Family Welfare, New Delhi.2012.
12. Govt. of India. 2005. DOTS Guidelines. Central TB Division, Directorate General of Health Services, Ministry of Health and Family Welfare, New Delhi.
13. Ahmed J, Chadha V K, Singh S, Venkatachalappa B, Kumar P. Utilization ofRNTCP services in rural areas of Bellary district, Karnataka, by gender, age and distance from health centre. Indian j tuberc 2009;56:62-8.
14. Mishra A, Mishra S,chouksy M, GautumP,Verma P, Srivastava D, Bansal M, gaur N, Patne S. A study of effectiveness of DOTS on Tuberculosis patients treated under RNTCP Program. NTI bulletin. 2007;43:47-50.
15. Gaikwad A,Deopujari K. A study of clinical profile and treatment outcome of DOTS regime in 250 Pulmonary and extra pulmonary tubercular patients in Hamida hospital, Bhopal, 2011. Chest. 2012;142:288-9.

Cite this article as: Sharma A, Kansal D, Katoch K, Sharma PK, Bansal R, Sharma T. Treatment outcome of new smear positive patients of pulmonary tuberculosis treated under directly observed treatment, short-course in a rural tertiary care hospital of a hilly area. Int J Community Med Public Health 2016;3:2129-32.