Original article:

A study on sputum conversion in new smear positive pulmonary tuberculosis cases at the end of intensive phase under DOTS regimen

Dr Ameena Syed[1],*Dr R .Nageswara Rao[2]

[1]Assistant Professor,
Department of Community Medicine,
Guntur medical college, Guntur.
[2]Professor and HOD ,
Department of Community Medicine,
Guntur medical college, Guntur.
Corresponding author*

ABSTRACT

Introduction: India's DOTS-based RNTCP Programme covered the entire country in 2006 March and it is implemented through primary healthcare system by Primary Health Centers and Sub Centers. This study has been taken to assess the treatment outcome of TB patients in terms of sputum conversion in 3 primary health centers of Dabeerpura TB unit at the end of intensive phase of DOTS regimen.

Materials and methods: A prospective study was done among 232 sputum smear positive tuberculosis patients after obtaining institutional ethical committee clearance and permission from concerned authorities.

Results: Of the 232 cases, 85% belonged to 15 – 49 years with 72% men and 28% women. Of them 79.74% were cured and total success rate was found to be 90%. Sputum conversion rate was 93.53% at the end of intensive phase.

Conclusion: In the present study, the sputum conversion rate by smear was 93.53% at the end of intensive phase of treatment. This is clearly more than RNTCPs objective of 90% smear conversion rate.

INTRODUCTION

Tuberculosis is an infectious disease caused by the bacillus Mycobacterium tuberculosis typically affecting the lungs (Pulmonary TB) but can also affect other sites (Extra pulmonary TB). This disease has existed for millennia and remains a major global health problem[1].

TB is the ninth leading cause of death worldwide and the leading cause from a single infectious agent,ranking above HIV/AIDS. The global incidence of TB was 10.4 million in 2016. There was an estimated 1.3 million TB deaths among HIV negative people and an additional 3, 74,000 deaths among HIV positive people in the same year[2]. Most of the incident cases in 2016 occurred in the WHO South East Asia Region[3]. The top five countries with 56% of estimated cases were India, Indonesia, China, Philippines and Pakistan[1]. From 2000 to 2015, global and national efforts to reduce the burden of TB were focussed on achieving targets set within the context of the Millennium Development Goals (MDGs)[1].In2016; the MDGs were succeeded by a new set of goals known as Sustainable Development Goals (SDGs).Most deaths from TB could be prevented with early diagnosis and appropriate treatment. TB control aims to reduce the spread of the infection and the most efficient method for preventing transmission is the identification and cure of infectious pulmonary TB patients[4].

www.ijbamr.com P ISSN: 2250-284X , E ISSN : 2250-2858

Sputum smear positive (SSP) pulmonary tuberculosis patients are the most significant source of infection for TB because, when they cough or sneeze, they expel droplet nuclei which carry infectious bacilli[5]. One untreated infectious TB patient is likely to infect 10-15 persons annually[6]. When SSP patients are initiated on multidrug ant tuberculosis treatment, there is a multifold reduction in bacillary load expelled in sputum[7]. It is expected that 80 to 90% of patients will undergo smear conversion within two to three months of treatment[8]. This research was done to study the sputum conversion rates in smear positive pulmonary tuberculosis cases at the end of intensive phase of DOTS treatment.

MATERIALS AND METHODS:

A prospective observational study was conducted among all newly diagnosed sputum smear positive TB cases under DOTS in Dabeerpura TB unit from 1st April 2012 to 30th September 2012. This TB unit has 3 Designated Microscopic Centre's namely the Saroor Nagar PHC, Vasanthalipuram PHC and Balapur PHC. Patients under Category 2 treatment were excluded. Information regarding their age, gender, occupation, habits, compliance to treatment and details regarding the sputum conversion were recorded in a separate performa after an interview with them at the respective primary health centres. Patients who did not report to health centres were followed up to their homes after getting their addresses from PHCs. Institutional ethical committee approval was taken prior to the study and permission was also obtained from the District TB Officer, State TB Officer , Medical Officer and concerned DOTS provider of the area. The data was entered in Microsoft Office Excel 2007 and IBM SPSS statistics 20 was used for analysis.

RESULTS:

From 1st April 2012 to 30th September 2012 , 232 cases of smear positive tuberculosis were diagnosed, which included 167 (72%) men and 65(28%) women. Almost 85% of the sputum smear positive cases belonged to 15-49 year age group followed by 11% in more than 50 years age group. Only a minority (3.45%) belonged to less than 14 years age group. Most (31%) of the study subjects were labourers ,literate (68.10%), married (65.95%), belonged to a nuclear family (83%), and were in the Class V socioeconomic status as per BG Prasad classification. Most of them(50.86%) were residing in a Pucca house but majority (58.62%) of the households of the patients were overcrowded as seen in Table 1.

The common complaints for which the study subjects contacted the health centres were persistent cough (65.95%), evening rise of temperature or prolonged fever (34%). 48.7% of the study subjects did not have any comorbidities. Among the comorbidities that were seen in the rest of the patients, diabetes (20.69%) and coinfection with HIV/AIDS (19.4%) topped the list.

All these patients were put on Category I DOTS through health care providers especially the community health workers and anganwadi workers. The Tuberculosis treatment cards were found to be filled and updated in 96.5% of the patients. The most commonest complaint in patients in whom DOTS was started was gastrointestinal upset which manifested as nausea and vomiting. It was noticed that 13.7% of them interrupted from treatment. 68.75% of them interrupted for less than 2 weeks duration. Rest of them were considered as defaulters. The main reasons for interruption of treatment was patient felt a sense of well being and due to adverse events. Out of 232 subjects, 79.74% were cured, 10.34% were considered as treatment completed, 1.72 % were dead, 2.16% were failures, 3.45% were defaulter after treatment and 2.59 % was transferred out as seen in Table 2. In total success rate of treatment was found to be 90% which shows high performance of TB Unit.

The sputum conversion at the end of 2nd month was 93.53%, at the end of 4th month it was 90.08% and at the end of treatment it was found to be 90.08% as seen in Table 3.

TABLE 1: BASELINE CHARACTERISTICS OF THE STUDY PARTICIPANTS

SNO.	VARIABLES	FREQUENCY (%)
AGE DISTRIBUTION		
1	≤ 14 YEARS	8 (3.45%)
2	15 – 49 YEARS	198 (85.34%)
3	≥ 50 YEARS	26 (11.21%)
GENDER		
1	MALE	167 (72%)
2	FEMALE	65 (28%)
OCCUPATION		
1	AGRICULTURAL LABOURER	7 (3.02%)
2	OTHER LABOURERS	96 (31.38%)
3	CULTIVATORS	16 (6.90%)
4	BUISNESS	4 (1.72%)
5	PROFESSIONAL	65 (28.02%)
6	UNEMPLOYED	44 (18.97%)
MARITAL STATUS		
1	MARRIED	153 (65.95%)
2	UNMARRIED	65 (28.02%)
3	WIDOWED/SEPERATED	14 (6.03%)
FAMILY TYPE		
1	NUCLEAR	193 (83.19%)
2	JOINT	39 (16.81%)
SOCIOECONOMIC STATUS		
1	CLASS I	6 (2.59%)
2	CLASS II	11 (4.74%)
3	CLASS III	39 (16.81%)
4	CLASS IV	74 (31.90%)
5	CLASS V	102 (43.97%)
TYPE OF HOUSE		
1	PUCCA	118 (50.86%)
2	SEMIPUCCA	78 (33.62%)
3	KUTCHA	36 (15.52%)
OVERCROWDING		
1	PRESENT	136 (58.62%)
2	ABSENT	96 (41.38%)

www.ijbamr.com P ISSN: 2250-284X , E ISSN : 2250-2858

TABLE 2: TREATMENT OUTCOME IN PATIENTS PUT ON DOTS CATEGORY 1

SNO.	FINAL OUTCOME	NO. OF PATIENTS (%)
1	CURED	185 (79.74%)
2	TREATMENT COMPLETED	24 (10.34%)
3	DIED	4 (1.72%)
4	FAILURE	5 (2.16%)
5	DEFAULTER AFTER TREATMENT	8 (3.45%)
6	TRANSFERRED OUT	6 (2.59%)

TABLE 3: RESULTS OF SPUTUM SMEAR EXAMINATION

SNO.	RESULT OF SPUTUM SMEAR EXAMINATION	At the end of IP/Extended IP		At the end of 2nd month CP		At the end of treatment	
		No.	%	No.	%	No.	%
1	DEFAULT	0	0.00	8	3.45	8	3.45
2	DIED	0	0.00	4	1.72	4	1.72
3	MIGRATED	0	0.00	6	2.59	6	2.59
4	NEGATIVE	217	93.53	209	90.09	209	90.09
5	POSITIVE	15	6.47	5	2.16	5	2.16

DISCUSSION:

This study was undertaken to gain insight into the proportion of patients who become sputum negative at the end of Intensive phase of DOTS treatment. The time of sputum conversion may be considered as a proxy measure for non infectiousness of the patient.

The patients were started on DOTS by the health care providers and were followed up by the investigators for the outcome. The outcome was measured by sputum smear conversion. The events in the patients, occurring during the treatment was also noted. Smear for AFB is a simple investigation and demands minimal resources and is also a recommended method for follow up examination as per Revised National Tuberculosis Control Program[9, 10]. However, it is not as sensitive method as culture[8], [11]. But in this study, culture of the sputum was not done due to financial constraints which is also a limitation of the study.

The treatment of patients under DOTS is basically of a domiciliary nature wherein patients need to take medication thrice weekly. A significant number of smear positive patients will become smear negative during the course of treatment and will respond favourably. In the present study, the sputum conversion rate by smear was 93.53% at the end of intensive phase of treatment. This is more than the 85% cure rate as mentioned in Millenium Development Goals[12]. The results obtained here are similar to a study done in Guwahati by Bawri S et al[13] where it was shown to be 92% and another study done by Dembele SM[14] where it was 92.1%.

In the present study, 15 (6.47%) of the patients still remained positive at the end of intensive phase of treatment. Category 1 patients who remained smear positive at the end of 3rd month of treatment where shifted to continuation phase. It was noted that 10 of them had undergone conversion during the continuation phase.

www.ijbamr.com P ISSN: 2250-284X , E ISSN : 2250-2858

Thus it was seen that 5 of the patients remained sputum smear positive even at the end of 5th month of treatment. One of the most important reasons for the patients to remain smear positive may be drug resistance. But drug resistance monitoring was not done in the present study. Wherever possible Drug susceptibility testing (DST) for all first line anti tuberculosis drugs should be done at the start of the treatment. Thus if resources were available, all 15 patients who remained positive at the end of intensive phase should have had a DST to rule out Multi Drug Resistance Tuberculosis (MDR TB). This should not be delayed till the end of 5 months as if done early, this could prevent drug resistant strains from spreading. This is especially important in a country like India where is a lot of primary drug resistant cases[15, 16].

There were 45 patients of tuberculosis who were positive for HIV. Patients who are HIV positive are at an increased risk of tuberculosis as well as MDR TB. Studies indicate that the time to smear conversion and culture conversion is either unaffected or shorter in patients with HIV / TB coinfection[17, 18]. MDR TB may itself be an important reason for late conversion. These patients added up with the non conversion patients are an important cause for default. This not only causes damage to the patient but also to the RNTCP program[19]. That is why early DST becomes important.

Awareness among patients about infection control measures is important. They should be taught to all patients and should be continued until they are proved to be non-infectious. The researchers believe that this should be continued atleast till sputum smear conversion. Better would be to wait for a few more weeks so that we give time for culture also to become negative. Thus the end of Intensive phase sputum smear examination can serve as a guide for removal of infection control measures.

CONCLUSION:

In the present study, the sputum conversion rate by smear was 93.53% at the end of intensive phase of treatment. This is clearly more than RNTCPs objective of 90% smear conversion rate. The patients have to be taught about infection control measures and the same has to be followed till they become non infectious.

REFERENCES:

1. Global tuberculosis report 2017.Geneva: World Health Organization;2017. Available at http://www.who.int/tb/publications/global_report/gtbr2017_main_text.pdf
2. Global Health Observatory Data. Tuberculosis. World Health Organization. Available at http://www.who.int/gho/tb/en/
3. Bulletin of the World Health Organization. Tuberculosis in the South East Asian Region. World Health Organization. Available at http://www.who.int/bulletin/volumes/88/3/09-073874/en/
4. Tsara V, Serasli E, Christaki P. Problems in diagnosis and treatment of tuberculosis infection. Hippokratia 2009;13(1):20-22.
5. Centres for Disease Control and Prevention. Guidelines for preventing the transmission of Mycobacterium tuberculosis in health care settings ,2005. MMWR 2005; 54[RR-17]:1-141.
6. Agarwal SP, Chauhan LS. Tuberculosis control in India. New Delhi , India: Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India,2005.
7. Brindle R, Odhiambo J, Mitchison D. Serial couints of Mycobacterium tuberculosis in sputum as surrogate markers of sterilizing activity of Rifampicin and Pyrazinamide in treating Pulmonary Tuberculosis. BMC Pulm Med2001; 1:2.
8. Frieden T. Toman's Tuberculosis case detection , treatment and monitoring. Questions and answers. Geneva, Switzerland: World Health Organization,2004.

9. Central TB Division. Revised National Tuberculosis Control Program. Technical and Operational Guidelines for Tuberculosis control. New Delhi, India : Dorectorate General of Health Services, Ministry of Health and Family Welfare, Government of India, 2005.
10. Central TB Division. Revised National Tuberculosis Control Program. Manual for Laboratory Technicians. Smear microscopy for detection of Acid Fast Bacilli. New Delhi, India: Dorectorate General of Health Services, Ministry of Health and Family Welfare, Government of India, 2009.
11. International Union against Tuberculosis Control and Lung Disease. Priorities for Tuberculosis bacteriology services for Low income countries. France, Paris: International Union against Tuberculosis Control and Lung Disease,2007.
12. World Health Organisation. WHO Report 2009. Global Tuberculosis Control Epidemiology, strategy, financing. Geneva, Switzerland:WHO Press, 2009.
13. S.Bawri, S. Ali, C Phukan,BTayal P.A Study of Sputum Conversion in New Smear Positive Pulmonary Tuberculosis Cases at the Monthly Intervals of 1st, 2nd & 3rd Month Under Directly Observed Treatment, Short Course (Dots) Regimen. Lung India 2008;25(3):118-123.
14. Dembele SM, Ouedraogo HZ, Combary A, Saleri N, Macq J, Dujardin BConversion rate at two-month follow-up of smear-positive tuberculosis patients in Burkina Faso.. www.ncbi.nlm.nih.gov/pubmed/18034956
15. Jain A, Mondal R, Prasad R, et al. Prevalence of multidrug resistant Mycobacterium tuberculosis in Lucknow, Utter Pradesh. Indian J Med Res 2008;128:300-6.
16. D'souza DT, Mistry NF, Vira TS, et al. High levels of multidrug resistant tuberculosis in new and treatment-failure patients from Revised National Tuberculosis Control Programme in an urban metropolis (Mumbai) in Western India. BMC Public Health 2009;9:211
17. Telzak EA, Fazal BA, Pollard CL, et al. Factors influencing time to sputum conversion among patients with smear-positive pulmonary tuberculosis. Clin Infect Dis 1997;25:666-70
18. Bwire R, Borgdorff MW, Sticht-Groh V, et al. Tuberculosis chemotherapy and sputum conversion among HIV seropositive and HIV seronegative patients in south-earthern Uganda. East AfrMed J 1999;76:307-313.
19. Parikh R, Nataraj G, Kanade S, Khatri V, Mehta P. Time to sputum conversion in smear positive pulmonary TB patients on Category I DOTS and factors delaying it. J Assoc Physicians India 2012; 60:22-26.