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Original Research Article

Sputum smear conversion rate of adult pulmonary tuberculosis patients under directly observed treatment shortcourse in Rajarajeswari Medical College and Hospital, Bangalore

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ABSTRACT

Background: Tuberculosis is among the most important causes of death from a single infectious agent and a major public health problem causing an enormous burden of disease and economic impact especially in the developing countries. Pulmonary tuberculosis is the most common form of tuberculosis causing >85% of all tuberculosis cases. The smear conversion rate is an operational indicator for the directly observed treatment short course (DOTS) strategy of Revised National Tuberculosis Control Programme (RNTCP) in India.
Methods: A longitudinal study was conducted in DMC, RRMCH, in the first two quarters of the year 2013 i.e., from January 1st to June 31st of the year 2013. All 130 adult category I (new) sputum smear positive cases that attended DMC, and registered under RNTCP constituted the sample for the study. Data was collected by interview method by using pre-tested, semi-structured questionnaire. Data was analyzed using SPSS version 20.0.
Results: Majority of the study subjects was >50 years, Hindus, illiterates, belonged to nuclear family from rural area belonged to upper lower socio-economic class. The overall sputum smear conversion rate is 92.4%. Lower sputum smear conversion rate was observed in the following risk factors like the male gender, smoking, diabetes, initial high pre-treatment smear grading and poor drug compliance.
Conclusions: The overall sputum conversion rate at the end of two months of intensive phase under (DOTS) chemotherapy in 118 sputum smear positive (cat I) new pulmonary tuberculosis patients in Designated Microscopy and Treatment Centre (DMC) Rajarajeswari Medical College and Hospital was 92.4%.

Keywords: RNTCP, Sputum smear conversion rate, Designated microscopy and treatment centre, Directly observed treatment short course, Intensive phase, Category I pulmonary tuberculosis

INTRODUCTION

Tuberculosis is among the oldest infection (more than 5000 years old) known to affect humans. It is among the most important causes of death from a single infectious agent and a major public health problem causing an enormous burden of disease and economic impact especially in the developing countries.[1,2]

Globally there were 8.6 million new tuberculosis cases in 2012 and 1.3 million tuberculosis deaths (just under 1.0 million among HIV-negative people and 0.3 million HIV-

associated tuberculosis deaths). The 1990 World Health Organization (WHO) report on the Global Burden of Disease ranked tuberculosis as the seventh most morbidity-causing disease in the world, and expected it to continue in the same position up to 20203.

India accounts for nearly 20% of the global burden of tuberculosis (TB), with global TB ranking of 'one'. It is the leading cause of death in patient with infectious diseases in India. Around 1.8 million people are detected to have tuberculosis every year in India, of which about 0.8 million are new smear positive highly infectious cases.[3,4]

Sputum smear positive (SSP) pulmonary tuberculosis patients are the most significant source of infection for tuberculosis. One untreated infectious tuberculosis patient is likely to infect 10 to 15 person annually.[5,6] For patients receiving Category-I regimen in the Revised National Tuberculosis Control Programme (RNTCP), smear conversion at the end of the intensive phase (IP) of treatment is emphasized as an important early predictor of treatment success. The sputum conversion results are used both for management of patients and for monitoring programme performance. If the smear is positive, the IP is extended by one more month for that patient.[6] Target cure rate is 85% under the Millennium Development Goal 7. In spite of various serological markers, qualitative sputum microscopy acid-fast bacilli (AFB) remain the important measure for the treatment response and diagnosis8. Change in the bacteriological status of sputum of patients from initial AFB positive to AFB negative after treatment is referred to as sputum smear conversion. Smear conversion rate (SCR) at two months of IP and at three months of IP (extended IP) is a significant operational indicator as it shows the capacity of the programme to maintain the patients on treatment. It also provides an objective evidence for the patient's response to therapy and hence the treatment outcome.[7,8]

The non-governmental agencies, private sector and the medical colleges play an important role in making RNTCP a success.[10] Medical college faculty, who are academicians are seldom directly involved in the implementation of national public health programmes. More than a decade ago for the first time in the global history of TB control, medical colleges of India were involved in the RNTCP of Government of India (GOI). For more than a decade, medical colleges have been providing diagnostic services (Designated Microscopy Centres), treatment [Directly Observed Treatment (DOT) Centres] referral for treatment, recording and reporting data, carrying out advocacy for RNTCP and conducting operational research relevant to RNTCP. As the programme widens the scope of services that it provides, medical colleges will have an increasingly important role to play in areas such as TB/HIV co-infection, external quality assurance of the sputum microscopy network, drug-resistance surveillance and management of multidrug-resistant TB patients. The RNTCP needs active support of medical colleges in carrying out operational research or in these areas to guide the development of the programme's future policies.[9-11]

Objectives

The objectives of the present study were to determine sputum smear conversion rate at the end of two months of intensive phase among category I (new) adult pulmonary tuberculosis patients attending Designated Microscopy and Treatment Centre in Rajarajeswari Medical College and Hospital and to describe socio demographic characteristics of study subjects.

METHODS

Source of data

All the category I knew sputum smear positive adult pulmonary tuberculosis patients who attended Designated Microscopy and Treatment Centre (DMC), Rajarajeswari Medical College and Hospital, Bangalore in first two quarters of the year 2013 i.e., from January to June 2013 were considered for the study.

Inclusion criteria

Newly diagnosed smear positive adult pulmonary tuberculosis cases, category I under DOTs were included.

Exclusion criteria

Extra pulmonary category I cases were excluded.

Study design

A longitudinal study.

Study setting

The study was conducted at Designated Microscopy and Treatment Centre (DMC), Rajarajeswari Medical College and Hospital, Bangalore, covering two lakh populations which comes under Konanakunte TB unit (TU).

Study duration

First two quarters of the year i.e., from January 1 to June 30th of the year 2013.

Study population

All adult category I (new) sputum smear positive cases who attended DMC, Rajarajeswari Medical College and Hospital, Bangalore registered under RNTCP.

Sample size

One hundred and thirty adult category I (new) sputum smear positive cases who attended DMC, Rajarajeswari Medical College and Hospital, Bangalore and registered under RNTCP in the first two quarters of the year 2013 i.e., from January 1st to June 30th constituted the sample for the study.

Study tools

A pre-tested, semi-structured questionnaire. Weight of the subjects was recorded by using standardized adult weighing machine. Subjects were made to empty the bladder and with their light weight cloth with pockets empty were made to stand on the weighing machine with their feet adequately spaced and head looking straight and both the arms by the side is then weighed on a bathroom scale (Zhongshan Camry Electronic Co. Ltd, Guangdong, China). The measurement was considered to the nearest decimal point of 0.5 kg. It was ensured that weighing machine was regularly standardized and calibrated during the study. Height was measured with a stadiometer to the nearest decimal and then converted to meters. Subjects are made to stand with bare foot and looking forward. BMI was calculated by dividing weight (kg) by height squared (m^2) and obesity defined as BMI greater or equal to 30 kg/m^2.

Method of data collection

A pilot study was conducted before the actual study, following which necessary changes were incorporated in the questionnaire before the actual study. These patients have been excluded for the main study.

Data collection was started after obtaining clearance from the institutional ethical committee, respective authorities from Lady Willingdon State TB Center and concerned DTO. Pretreatment smear grading was obtained from RNTCP lab sputum register. The 130 new sputum smear positive patients on their first contact were explained about the purpose of the study and a written informed consent was taken. Data was collected from the patients by interview method by using pre-tested, semi-structured questionnaire. The study variables including sociodemographic characteristics, treatment taken, clinical history, history of contact, history of habits and any co-morbidity were collected at their first visit. Patient's complete address, TB number and phone number were noted down for their follow up. The patients were followed up for compliance of the drugs. Patients compliance was identified by treatment cards, if they failed to return for drug collection less than three times a week was considered poor compliance and if they returned for drug collection three days a week was considered good compliance.

After the completion of two months of intensive phase of treatment the patients were followed up for the sputum smear examination to know about sputum smear conversion by quality sputum microscopic examination.

The reports were collected from RNTCP lab sputum register and patient's treatment cards.

Statistical analysis

The data was compiled in Microsoft Excel work sheet and analyzed using Statistical Package for Social Sciences (SPSS) software version 20.0.

Descriptive statistics

All qualitative variables are presented as frequency and percentages. Chi-square test of significance was used and Fisher's exact test was used when the expected value of a cell was less than 5. P values of less than 0.05 were considered statistically significant. Microsoft word and Excel have been used to generate graphs, tables.

RESULTS

In the present study which was conducted at Designated Microscopy and Treatment Centre (DMC), Rajarajeswari Medical College and Hospital, Bangalore, the following observations were made.

The socio-demographic characteristics were, maximum number of patients were in the age group of >50 years, majority were males 91 (70.0%), Hindus 112 (86.1%), 102 (78.5%) were married, 106 (81.5%) stayed in a nuclear family, 75 (57.7%) were from rural area, 60 (46.2%) were illiterate, 55 (42.3%) were unskilled workers and 83 (63.8%) belonged to (class IV) upper lower class (Figure 1) (Table 1).

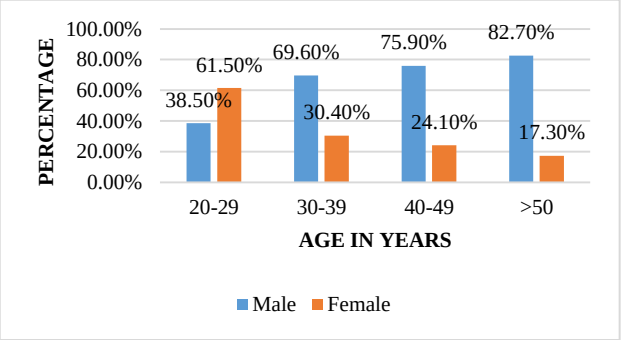

Figure 1: Distribution of patients according to age and gender.

Majority of the patients 71 (54.6%) were in underweight category, 51 (39.2%) were in normal weight category, 7 (5.4%) were in overweight, 1 (0.8%) was in pre-obese category (Figure 2).

Habits of the patients were, 71 (54.6%) were smokers, 20 (15.4%) patients had a history of tobacco consumption and 69 (53.1%) patients were alcoholics.

Co-morbidity pattern among patients was 31 (23.8%) were diabetics, 6 (4.6%) patients were HIV positive and majority of the patients 71 (54.6%) were in underweight category (Table 2).

Table 1: Sociodemographic profile of the study participants (n=130).

Variable		Frequency (%)
Locality	Rural	75 (57.7)
	Urban	28 (21.5)
Religion	Hindu	112 (78)
	Muslim	17 (13.1)
	Christian	01 (0.8)
Type of family	Nuclear	106 (81.5)
	Joint	23 (17.7)
	Three generation	01 (0.8)
Socioeconomic status (modified 2012 Kuppuswamy classification)	I	-
	II	06 (4.6)
	III	26 (20.0)
	IV	83 (63.8)
	V	15 (11.6)
Education	Literate	70 (53.8)
	Illiterate	60 (46.2)
Occupation	Unemployed	34 (26.1)
	Employed	96 (73.9)
Marital status	Married	102 (78.5)
	Unmarried	28 (21.5)

Table 2: Habits and comorbidity of the study subjects (n=130).

Variable		Frequency (%)
Habits	Smoking	71 (54.6)
	Tobacco	20 (15.4)
	Alcohol	69 (53.1)
Comorbidity	Diabetes	31 (4.6)
	HIV	6 (13.1)
BMI	Underweight	71 (54.6)
	Normal	51 (39.2)
	Overweight	07 (5.4)
	Pre obese	01 (0.8)

Pretreatment smear grading showed that, most of the patients 60 (46.2%) had 1+ smear grading, 27 (20.8%) patients had 2+ smear grading, 24 (18.5%) patients had 3+ smear grading, and 19 (14.5%) patients had scanty smear grading (Figure 3).

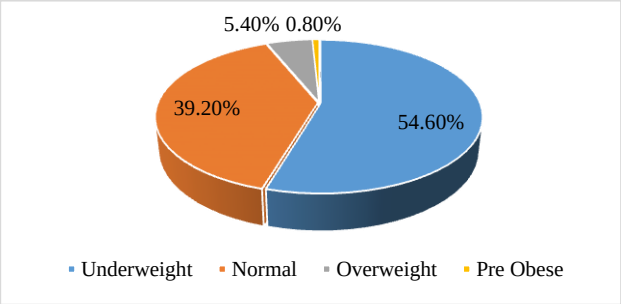

Figure 2: Distribution of patients according to body mass index.

Major factor for delay in seeking health care facilities was lack of knowledge about the disease, majority of patients 109 (83.8%) had good drug compliance (Table 3).

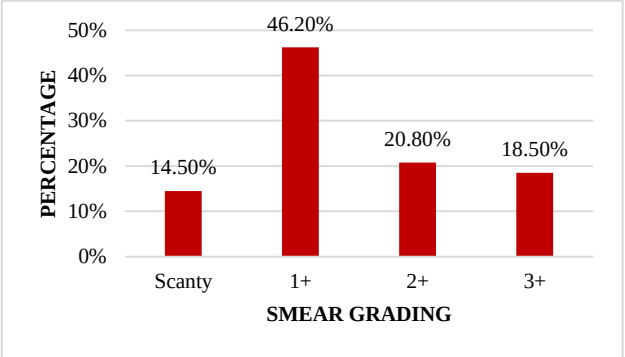

Figure 3: Pre-treatment smear grading of the patients.

Out of 130 patients 11 (8.5%) of the patients died, 1 (0.8%) patient defaulted. So the total number of patients were 118. Out of 118 patients 9 (7.6%) remained smear positive, 109 (92.4) converted to smear negative (Table 4).

Lower sputum smear conversion rate was observed in the following factors like age, alcohol consumption, HIV status and BMI (Table 5).

The overall sputum smear conversion rate is 92.4%. Lower sputum smear conversion rate was observed in the following factors like the male gender, smoking, diabetes, initial high pre-treatment smear grading and poor drug compliance which were statistically significant (Table 6).

Table 3: Factors for delay in seeking health care facilities and drug compliance (n=130).

Factors for delay in seeking health care facilities	Frequency	%
No knowledge about the disease	71	54.6
No care taker	15	11.6
Not aware of facility	44	33.8
Total	130	100.0
Drug compliance		
Good	109	83.8
Poor	21	16.2
Total	130	100.0

Table 4: Sputum smear conversion rate (excluding defaulters and dead) (n=118).

Sputum smear conversion	Frequency	%
Positive	09	7.6
Negative	109	92.4
Total	118	100.0

Table 5: Factors associated with sputum conversion rate.

Factors		Sputum smear conversion at the end of intensive phase (2 months)		Total
		Positive	Negative	
Age (in years)	20-29	-	25 (100.0)	25 (100.0)
	30-39	01 (5.0)	19 (95.0)	20 (100.0)
	40-49	01 (3.7)	26 (96.3)	27 (100.0)
	>50	07 (15.2)	39 (84.8)	46 (100.0)
Alcohol	Yes	6 (10.2)	53 (89.8)	59 (100.0)
	No	3 (5.1)	56 (94.9)	59 (100.0)
	Total	9 (7.6)	109 (92.4)	118 (100.0)
HIV	Yes	02 (33.3)	04 (66.7)	06 (100.0)
	No	07 (6.3)	105 (93.7)	112 (100.0)
	Total	09 (7.6)	109 (92.4)	118 (100.0)
BMI	Under weight	6 (9.5)	57 (90.5)	63 (100.0)
	Normal	3 (6.4)	44 (93.6)	47 (100.0)
	Overweight	-	7 (100.0)	7 (100.0)
	Pre-obese	-	1 (100.0)	1 (100.0)

Table 6: Factors associated with sputum conversion rate.

Factors		Sputum smear conversion at the end of intensive phase (2 months)		Chi square/ Fisher exact test	P value
		Positive	Negative		
Gender	Male	9 (11.3)	71 (88.7)	Fisher exact test	p<0.05
	Female	-	38 (100.0)		
Smoking	Yes	8(13.1)	53 (86.9)	Fisher exact test	p<0.05
	No	1 (1.8)	56 (98.2)		

Continued.

Factors		Sputum smear conversion at the end of intensive phase (2 months)		Chi square/ Fisher exact test	P value
		Positive	Negative		
Diabetes	Yes	5 (18.5)	22 (81.5)	Fisher exact test	p<0.05
	No	4 (4.4)	87 (95.6)		
Pretreatment smear grading	Scanty	-	17 (100.0)	X^2=8.145 Df-3	p<0.05
	1+	02 (3.4)	56 (96.6)		
	2+	03 (13.0)	20 (87.0)		
	3+	04 (20.0)	16 (80.0)		
Compliance	Good	01 (0.9)	108 (99.1)	Fisher exact test	p<0.05
	Poor	08 (88.9)	01 (11.1)		

DISCUSSION

In our study socio-demographic characteristics were, maximum number of patients were in the age group of >50 years, majority were males 91 (70.0%), Hindus 112 (86.1%), 102 (78.5%) were married, 106 (81.5%) stayed in a nuclear family, 75 (57.7%) were from rural area, 60 (46.2%) were illiterate, 55 (42.3%) were unskilled workers and 83 (63.8%) belonged to (class IV) upper lower class.

Study done by Gopikrishna et al observed that sputum positivity was maximum in age group 20-39 years i.e., (39.0%) more among males i.e., 39.8% specially Hindus i.e., (40.1%).[12] Majority of the study subjects i.e., 52.5% belong to joint family, (42%) were from rural area (30%) were illiterates.

Habits of the patients were 71 (54.6%) were smokers, 20 (15.4%) patients had a history of tobacco consumption and 69 (53.1%) patients were alcoholics.

Study done by D'Souza et al showed that 38.3% had the habit of drinking alcohol and taking tobacco, 63.3% had consumed tobacco or alcohol for more than five years.[13]

In our study co-morbidity pattern among patients was 31 (23.8%) were diabetics, 6 (4.6%) patients were HIV positive.

Mota et al showed that out 136 TB patients 15 (11.05%) were HIV positive 121 (89.0%) were HIV negative.[14]

Viswanathan et al showed that age, BMI, positive family history of DM and sedentary occupation were the common risk factors associated with diabetes among TB patients.[15]

In our study majority of the patients 71 (54.6%) were in underweight category. Pretreatment smear grading showed that, most of the patients 60 (46.2%) had 1+ smear grading, 27 (20.8%) patients had 2+ smear grading, 24 (18.5%) patients had 3+ smear grading, and 19 (14.5%) patients had scanty smear grading.

Gopi et al showed that out of 1463 patients, 43 patients had scanty smear grading, 562 patients had 1+ smear grading, 374 patients had 2+ smear grading, 484 patients had 3+ smear grading.[16]

Majority of patients 109 (83.8%) had good drug compliance in our study,

Pandit et al showed that, out of 100 patients, 93 patients are compliant with the treatment and they also observed that compliances not associated with any socio-demographic factors.[17]

In the present study, the overall sputum smear conversion rate is 92.4%. Lower sputum smear conversion rate was observed in the following factors like the male gender, smoking, diabetes, initial high pre-treatment smear grading and poor drug compliance.

Similarly, Bawri et al showed that the overall sputum conversion rate under DOTS chemotherapy in 100 sputum smear positive pulmonary tuberculosis patients in DOTS Centre, Gauhati Medical College and Hospital was 92%.[18] Lower sputum smear conversion rate was observed in the following factors like the male gender, smoking, diabetes, initial high pre-treatment smear grading and poor drug compliance.

CONCLUSION

The overall sputum conversion rate at the end of two months of intensive phase under DOTS chemotherapy in 118 sputum smear positive (cat I) new pulmonary tuberculosis patients in Designated Microscopy and Treatment Centre (DMC) Rajarajeswari Medical College and Hospital is 92.4%. Lower sputum smear conversion rate was observed in the following risk factors like the male gender, smoking, diabetes, initial high pre-treatment smear grading and poor drug compliance.

Recommendations

Compliance towards the treatment must be emphasized which has an impact on early sputum smear conversion. Awareness should be created at community level regarding tuberculosis, for early diagnosis and treatment. Private medical colleges can act as a single window for providing information and taking the responsibility of treatment initiation until cure.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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