ORIGINAL ARTICLE

EVALUATION OF TREATMENT OUTCOME OF PULMONARY TUBERCULOSIS PATIENTS ON CATEGORY I AND CATEGORY II DOTS

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ABSTRACT:
Aim and objectives - To study the outcome of pulmonary tuberculosis patients on category I and category II DOTS. **Material and method-** The present study was carried out in the department of Pulmonary Medicine, Guru Gobind Singh Medical College and Hospital Faridkot, Punjab from April 2015 to November 2016 on pulmonary TB patients registered under category I and category II DOTS. Detailed history including past history of anti- tubercular drugs was recorded after taking written and informed consent and detailed systemic examination was carried out as per the proforma attached. **Results-** In category I treatment group maximum number of patients (64%) was treatment completed followed by cured patients (28%) followed by lost to follow up (4%). Two percent of patients died and 2% patients were not evaluated. Treatment success rate (cure + treatment complete) was 92% for category I patients. In category II treatment group maximum number of patients (52%) were cured followed by treatment completed patients (32%) followed by treatment failure (6%). Six percent of patients died, 2% patients defaulted and 2% patients were not evaluated **Conclusion-** Overall success rate was 88%. The cure/ treatment completion rate in category I and category II patient in present study was 92% and 84% respectively. Default rate of 3 %, failure rate of 3% and death rate of 4% was observed in our study. In our study the success rate was 88%.The treatment success rate in category I and category II patient was 92% and 84% respectively which was higher than National figures. Better outcome was observed among category I patients as compared to category II patients.
Key words: DOTS, Pulmonary, tuberculosis.

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INTRODUCTION

Tuberculosis is a specific infectious disease caused by Mycobacterium tuberculosis. The disease primarily affects lungs and causes Pulmonary tuberculosis. It can also affect intestine, meninges, bones and joints, lymph glands, skin and other tissues of the body [1] The disease is usually chronic with cardinal features like persistent cough with or without expectoration, intermittent fever, loss of appetite, weight loss, chest pain, night sweats and haemoptysis. Hippocrates (460-377 B.C.) called this disease "pthisis", a Greek word which meant "to consume", "to spit" and "to waste away". Oliver Wendell referred to the disease as "white plague". In Sanskrit, the disease has been called "rajayakshma","ksayah", and" Sosa". The word "tuberculosis" is a derivative of the Latin word "tuberculoma" which means "a small lump" [2] It is transmitted from person to person via droplets from the throat and lungs of people with the active respiratory TB disease. TB is also called Koch's disease, after the name of scientist Robert Koch, who identified and described the Mycobacterium tuberculosis on 24 March, 1882 [3] It is estimated that the one third of the world population is latently infected with M. tuberculosis and only 5-10% of these individual develop TB some time in their lifetime when their immune system is compromised due to ageing, malnutrition, physical stress, immunosuppressive drugs, diabetes and Human Immunodeficiency Virus infection [4] .The first genuine success in immunization against tuberculosis was developed from attenuated bovine-strain tuberculosis by Albert Calmette and Camille Guerin in 1906. It was called "BCG" (Bacillus of Calmette and Guerin) [5] .Drug-resistant TB is a public health issue in many developing countries, as treatment is longer and

requires more expensive drugs. Multi drug resistant tuberculosis (MDR-TB) is defined as resistance to the two most effective first-line TB drugs: rifampicin and isoniazid with or without resistance to other first line drugs tested from a national accredited laboratory. Extensively drug-resistant TB (XDR-TB) is defined as MDR TB case whose recovered M. tuberculosis isolate is resistant to at least isoniazid, rifampicin, a fluoroquinolone (ofloxacin, levofloxacin, or moxifloxacin) and a second-line injectable anti TB drug (kanamycin, amikacin, or capreomycin) from a RNTCP-certified Culture & DST Laboratory. [6]

MATERIAL AND METHOD

The present study was carried out in the department of Pulmonary Medicine, Guru Gobind Singh Medical College and Hospital Faridkot, Punjab from April 2015 to November 2016 on pulmonary TB patients registered under category I and category II DOTS. Detailed history including past history of anti- tubercular drugs was recorded after taking written and informed consent and detailed systemic examination was carried out as per the proforma attached. Study subjects: 50 consecutive cases of pulmonary tuberculosis on category I DOTS treatment and 50 consecutive cases of pulmonary tuberculosis on category II DOTS were included in the study. Inclusion criteria: Pulmonary tuberculosis patients registered for category I DOTS and category II DOTS treatment in department of Pulmonary Medicine at Guru Gobind Singh Medical College and Hospital Faridkot. Exclusion criteria: Extra pulmonary tuberculosis , Patients below 14 years of age , Patients already on DOTS or patients on treatment from private sector for pulmonary tuberculosis were not included in the study , HIV positive patients, Pregnant and lactating women . Investigations done before the start of treatment: Hb, TLC , DLC ,RBS ,HIV status, Sputum examination for Acid Fast bacilli-Sputum examination was done under direct microscopy by Auramine Rhodamine staining before the start of treatment and at 2, 6 months in category I and at 3, 8 months in category II. If the sputum was positive in category I and category II after 2 and 3 months respectively, intensive phase was prolonged for one more month and sputum was sent for culture and drug sensitivity testing (CBNAAT). Then again sputum examination was done at the end of extended intensive phase.

PATIENTS WERE CLASSIFIED INTO TWO CATEGORIES

Category I	New sputum smear positive New sputum smear negative New others
Category II	Sputum smear positive relapse Sputum smear positive failure Sputum smear positive after lost to follow up Others

DRUG REGIMENS USED IN TWO CATEGORIES:

Category I: 2 (HRZE)3   4(HR)3
Category II: 2(SHRZE)3   1(HRZE)3 5(RHE)3

In category I drugs were given in the form of Isoniazid (H), Rifampicin (R), Pyrazinamide (Z), Ethambutol (E) for a period of two months thrice a week on alternate days followed by R & H for four months thrice a week on alternate days.
In category II drugs were given in the form of Streptomycin (S), Isoniazid (H), Rifampicin (R), Pyrazinamide (Z) and Ethambutol (E) for a period of 2 months thrice a week on alternate days followed by R, H, Z and E .

DRUG DOSAGE:

Isoniazid 600 mg ,Rifampicin 450 mg , Pyrazinamide 1500 mg , Ethambutol 1200 mg ,Streptomycin 750 mg

OUTCOME was assessed in the following heads:
– Treatment failure
– Treatment default/ loss to follow-up
– Smear conversion
– Cure
– Death
– Treatment completed
– Not evaluated
– Treatment success (treatment completed + cure)

STATISTICAL ANALYSIS: Assessment of different outcome variables were calculated in terms of percentages on excel program. Data were analyzed using SPSS PC software. Association between categorical variables was assessed using two-tailed $\chi 2$ tests. P values of <0.05 were considered to indicate statistical significance.

RESULTS-

Current study was performed in Department of Pulmonary Medicine at Guru Gobind Singh Medical College and Hospital. In this study 50 patients on category I DOTS and 50 patients on category II DOTS were included. The aim of the study was to evaluate the outcome of pulmonary tuberculosis patients on category I and category II DOTS . All patients were subjected to detailed history after taking written and informed consent and detailed systemic examination was carried out. Following observations were recorded: Demographical markers : Age, Sex, Geographic distribution Adverse drug effects Data were analyzed using SPSS PC software. Association between categorical variables was assessed using two-tailed $\chi 2$ tests. P values of <0.05 were considered to indicate statistical significance.

Table 1: Age wise distribution of cases in the study

Age	Male		Female		Total
	No. of patients n=53	percentage	No. of patients n= 42	percentage	
15-34	29	54.7	20	42.5	49
35-54	15	28.3	14	29.8	29
55-74	9	17	11	23.4	20
>75	0	0	2	4.3	2

$\chi 2 = 3.540$ df = 3   p > 0.05

TABLE 2 - Age wise distribution of patients in two treatment groups

Age group	Category 1		Category 2		Total
	No. of patients	Percentage	No. of patients	Percentage	
15-34	21	42	28	56	49
35-54	14	28	15	30	29
55-74	14	28	6	12	20
>75	1	2	1	2	2

$\chi 2 = 4.234$ df = 3   p > 0.05

Maximum number of cases was between 15 to 34 years of age as shown in the table 2. Only 2% patients were in the age group of greater than 75 years. There was no statistically significant difference observed in the age wise distribution of the patients in two treatment groups (p>0.05). Mean age of patients was 37.39 ± 17.42years in the study. Mean age in category I patients was 39.40 ± 19.00 years, while in category II patients was 35.38 ± 15.623 years.

TABLE 3 -Gender wise distribution of cases in two treatment groups

Gender	Category 1		Category 2		
	No. of the patients	percentage	No. of patients	percentage	Total
Male	27	54	26	52	53
Female	23	46	24	48	47

$\chi 2 = 0.040$ df = 1   p > 0.05

In this study of one hundred patients, fifty three were males and forty seven were females. The difference in gender wise distribution of category I and category II patients was not found statistically significant (p=0.841).

TABLE 4- Geographical distribution of patients in the study

	Rural	Urban	Total
Category 1	28	22	50
Category 2	26	24	50
Total	54	46	100

$\chi 2 = 0.161$ df = 1   p > 0.05

In our study 54% patients were from rural area while 46% patients were from urban area. In category I treatment group 28 patients (56%) belonged to rural area and 22 patients (44%) belonged to urban area. In category II treatment group 26 patients (52%) were from rural area and 24 patients (48%) were from urban area. There was found no statistically significant difference in rural and urban area wise distribution of patients in two treatment groups.

TABLE 5- Category wise distribution of patients according to their clinical presentation profile

Symptoms	Category 1		Category 2		Total
	Cases	Percentage	Cases	Percentage	
Fever	45	90	44	88	89
Cough	47	94	49	98	96
Shortness of breath	21	42	22	44	43
Haemoptysis	7	14	8	16	15
Chest pain	1	2	7	14	8
Loss of appetite	31	62	26	52	57
Weight loss	22	44	20	40	42
Abdominal pain	0	0	3	6	3

The above table shows that the major complaint in the study group was cough which was present in 96% patients followed by fever which was present in 89% patients. There was no significant difference observed in the symptoms of the patients in two groups except for chest pain which was statistically significant (p=0.027).

Table 6- Distribution of patients in category II group according to their previous treatment status

Type of the patients	Category 2	
	No. of the cases	Percentage
Relapse	28	56
TAF	5	10
TLU	17	34
Total	50	100

TAF= Treatment after failure,
TLU= Treatment after lost to follow up

According to RNTCP guidelines only new patients were included in category I group, while category II group included previously treated patients i.e. relapse, treatment after failure, treatment after lost to follow up and others. In this study maximum cases (56%) were found to be in relapse group followed by treatment after lost to follow up (TLU) group (34%) followed by treatment after failure (TLF) (10%).

TABLE 7- Category wise sputum status before the start of treatment

Category	Patients	Sputum Status		Ne
		Positive	Negative	
Category 1	50 (N=50)	16 (32%)	33 (66%)	1 (2%)
Category 2	50 (N=50)	31 (62%)	19 (38%)	0
Total	100	47	52	1

$\chi2 = 9.556$ df = 2   p < 0.05

NE = Patient not expectorating sputum The above table shows that 47% of patients were sputum positive, 52% were sputum negative and 1% patients did not produce any sputum at the start of treatment. The number of sputum negative patients was more in category I patients (66%), while the number of sputum positive cases was more in category II patients (62%). This difference in the distribution of sputum status at the start of treatment in two category groups was found to be statistically significant (p < 0.05).

TABLE 8- Category wise sputum status of the patients at the end of treatment

Category	Patients	Sputum status		Patients not expectorating sputum	Sputum examination not done
		positive	negative		
Category 1	50	0	44	2	4
Category 2	50	3	40	2	5
total	100	3	84	4	9

$\chi2 = 3.179$ df = 1   p > 0.05

At the end of treatment 84 cases were sputum negative, 3 cases were positive, 13 (9+4) cases were not available for examination of sputum (because of lost to follow up, death, transfer out or non-expectoration of sputum). In category I patients, 44 (88%) were sputum negative and none was sputum positive at the end of treatment. In category II patients, 40 (80%) were sputum negative and 3 (6%) were sputum positive at the end of treatment. This distribution of patients in two treatment groups according to sputum status at the end of treatment was found to be statistically insignificant (p>0.05).

TABLE 9- Treatment outcome of patients in the category I

Outcome	Category 1	
	No. of patients	Percentage
Cure	14	28
Treatment complete	32	64
LTFU	2	4
TREATMENT FAILURE	0	0
Died	1	2
Not evaluated	1	2
Total	50	100

LTFU: Lost to follow up

In category I treatment group maximum number of patients (64%) was treatment completed followed by cured patients (28%) followed by lost to follow up (4%). Two percent of patients died and 2% patients were not evaluated. Treatment success rate (cure + treatment complete) was 92% for category I patients

TABLE 10- Treatment outcome of patients in the category II

Category 2		
Outcome	No. of patients	Percentage
Cure	26	52
Treatment complete	16	32
LTFU	1	2
Treatment failure	3	6
Died	3	6
Not evaluated	1	2
Total	50	100

In category II treatment group maximum number of patients (52%) were cured followed by treatment completed patients (32%) followed by treatment failure (6%). Six percent of patients died, 2% patients defaulted and 2% patients were not evaluated. Treatment success rate (cure + treatment complete) was 84% for category II patients. Number of cured patients was more in category II (52%) than category I (28%) treatment group and this distribution of cured patients in the two groups was found to be statistically significant (P< 0.05). This difference in the number of the cured patients can be attributed to more sputum positivity in category II patients. Treatment completion rate was 64% for category I and 32% for category II patients. Treatment completion rate was more in category I than category II patients and the difference between the two groups was statistically significant (P< 0.05).

TABLE 11- Treatment outcome of the patients in the study

Outcome	No. of patients	Percentage
Cure	40	40
Treatment completed	48	48
LTFU	3	3
TREATMENT FAILURE	3	3
Died	4	4
Not evaluated	2	2
Total	100	100

In our study of 100 patients treatment success rate (cure + treatment completed) was 88%. 3% cases defaulted, 3% cases failed to treatment, 4% died and 2% were not evaluated.

DISCUSSION-
The present study was carried out in the department of Pulmonary Medicine, Guru Gobind Singh Medical College and Hospital, Faridkot, Punjab on pulmonary TB patients registered under category I and category II DOTS.

Fifty consecutive cases of pulmonary tuberculosis on category I DOTS treatment and 50 consecutive cases of pulmonary tuberculosis on category II DOTS were included in the study. All new pulmonary Tuberculosis cases were put on category I treatment while relapse, defaulter, failure and other cases were put on category II treatment. In this study of 100 patients with age ranging from 15-80 years, patients were divided into 4 age groups. Maximum number of cases (49%) was observed between 15 to 34 years of age group followed by 35 to 54 years (29% patients) age group. Furthermore, there was no statistically significant difference observed in the age wise distribution of the patients in two treatment groups (p>0.05). Similar distribution of patients was observed by Sandeep Singh Sarpal et al in 2010 with maximum patients in the age 87 group of 25-34 years (25.3%). [7] So, maximum number of patients occur in young and middle age group. Our study showed that mean age of the patients was 37.39 ± 17.42 years, Mean age in category I patients was 39.40 ±19.00 years and in category II patients was 35.38 ±15.62 years. Similar results were observed by Nafisa Batool Tahir et al in 2008 [8] and Sandeep Singh Sarpal et al in 2010 [7] with mean age of patients 34.61 years and 35.92 ± 15.42 years (p = 0.928) respectively. In our study no gender preponderance was observed. Out of 100 patients, 53% were male and 47% were female patients. Likewise gender distribution of category I and category II patients was not found statistically significant (p=0.841). Egbewale BE et al 2000 carried out a study on 879 patients including 467(53.1%) males and 412 (46.9%) female patients[9] Choudhary Sumer et al in 2006 observed that out of 141 patients, 98 (69.5%) were male and 43 (30.5%) were female patients[10] In the study by Kumar A et al 2010, 68% were males and 32.0% were females. [11] Kavita Vasudevan et al 2011 observed 68.8% were male and 31.2% were female in the 660 patients. [12] So the number of male and female patients varies in different studies in accordance with study area and sample size. Major complaint in our study group was cough (96%) followed by fever (89%) followed by loss of appetite (57%), breathlessness (43%), weight loss (42%). Moreover, there was no statistical significant difference in the symptoms of the patients in category I and category II patients (except for chest pain which was observed more in category II patients). Abinash Agarwala et al 2011 observed similar complaints of cough (92.1%) and fever (84.2%), followed by weight loss, anorexia, and hemoptysis in the study population. [63] Saibal Moitra et al 2014 observed that 83% of the total patients had cough, followed by 76% who had weight loss and 70% who had fever as their primary symptom [13] Fifty new patients were included in category I treatment group while 28 (56%) relapse cases, 17 (34%) treatment after lost to follow up and 5 (10%) treatment after failure cases were included in category II treatment group. In the study by Jayant B Chauhan et al 1999; 12.6% relapse cases, 12.6% treatment after failure cases and

63.5% treatment after lost to follow up and 11.3% other patients were studied under category II [14] Another study by Karma G Dolma et al in 2002, relapse cases 1185(63.8%) were found to be the most common in the category II; followed by failure cases 387(20.8%) and treatment after default cases 283(15.2%) [15] In a study by Sarpal SS et al 2010 of category II patients 264 (48.4%) were relapse patients, 167 (30.6%) belonged to others category, 75(13.8%) were on treatment after default, 39 (7.2%) were failure cases.[7] Thus the distribution of the patients in the category II patients vary in different studies according to the previous treatment outcome. 47% of patients were sputum positive at the start of treatment and 52% were sputum negative while 1% patients did not expectorate sputum. 27.5% patients were found to be sputum smear positive and 72.5% patients were sputum smear negative in a study of 768 patients by Mohammad Tahir et al 2001 [16] There is need to improve the sputum smear microscopy to improve the sputum positivity at the start of treatment. In our study majority of the patients (84%) were sputum negative at the end of intensive phase. 5% cases were sputum positive at the end of intensive phase. In these sputum positive patients, Intensive phase was prolonged for 1 month and sputum was sent for DST. Sputum conversion rate at the end of intensive phase was 85.1% (40/47). The sputum conversion rate in the new smear positive cases was 93.8% in a study by NK Goel et al in 2004-2005.[17] Similar results were observed by Kavita Vasudevan et al 2011 with sputum conversion rate of 85.1% in 403 smear positive TB patients. [12] The sputum conversion rate was 87.5% (14/16) for patients on category I treatment and 83.8% (26/31) for patients on category II treatment respectively. Higher sputum conversion rate in category I patients than in category II patients was observed in different studies. Mishra et al 2006 observed sputum conversion rate of 92.5% and 56% [18] for Category I and Category II respectively. Similar results observed by Kavita Vasudevan et al 2011 with sputum conversion rate 88.5% and 76.9% for Category I and Category II respectively.[12] The treatment success rate in category I and category II patient in present study was 92% and 84% respectively and overall success rate was 88%. Success rate was higher among category I patients. The treatment success rate of tuberculosis patients was high compared to national figures (which were 88% for category I patients and 75% for category II patients in 2013).Belete Getahun et al in 2004 documented treatment success of 82.7% in their study [19] Success rate of 85.04% was observed by A. Mishra et al 2006 in patients on category I treatment [20] Asmamaw Malede et al 2010 observed 1,331(88.1%) cases were successfully treated at Dessie and Woldiya Town Health Institutions, Northeast Ethiopia [21]. Balkrishan Lanjewar et al 2011 found that out of 429 subjects, 334(77.8%) were successfully completed the treatment [22] Death rate of 4%, failure rate of 3% and default rate of 3% was observed in our study. Belete Getahun et al 2004

observed that 3.7% patients died during follow-up, 0.4% failed to treatment, 5.1% defaulted, and 8.2% transferred out to another health institution[23] Asmamaw Malede et al 2010 observed 123 (8.1%) died, 12 (0.8%) failed from treatment and[24] .

CONCLUSION-

Maximum number of cases (49%) was observed between 15 to 34 years of age group followed by 35 to 54 years (29% patients) age group. Mean age of the patients in the study was 37.39 ± 17.42 years. Mean age in category I patients was 39.40 ± 19.00 years and category II patients was 35.38 ± 15.62 years. Out of 100 patients 53% were males and 47% were females. 54% patients belonged to rural area while 46% patient belonged to urban area. Major complaint in the study group was cough which was present in 96% patients followed by fever which was present in 89% patients. All 50 cases in category I group were new patients, while there were 28 (56%) relapse cases, 5 (10%) treatment after failure cases and 17 (34%) treatment after lost to follow up were included in category II group. 47% of patients were sputum positive and 52% were sputum negative while 1% patients were those who did not produce any sputum at the start of treatment. Sputum conversion at the end of intensive phase was 85.1% (40/47). It was 87.5% (14/16) for category I patients and 83.8% (26/31) for category II patients. 84% of patients were sputum negative and 3% were sputum positive, 4% patients were those who did not produce any sputum and 9% were not evaluated for sputum (because of lost to follow up, treatment failure, death, transfer out) at the end of treatment. Overall success rate was 88%. The cure/ treatment completion rate in category I and category II patient in present study was 92% and 84% respectively. Default rate of 3 %, failure rate of 3% and death rate of 4% was observed in our study. In our study the success rate was 88%.The treatment success rate in category I and category II patient was 92% and 84% respectively which was higher than National figures. Better outcome was observed among category I patients as compared to category II patients.

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