

A PROSPECTIVE STUDY OF SPUTUM CONVERSION RATE AND CURE RATE IN SMEAR POSITIVE RETREATMENT PATIENTS UNDER RNTCP IN RURAL POPULATION

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ABSTRACT: BACKGROUND AND OBJECTIVES: Directly Observed Treatment, Short course (DOTS) is the name of the World Health Organization (WHO) recommended TB (Tuberculosis) control strategy. It is vital for the success of the TB control program. This study has been taken up to assess the compliance, bacteriological sputum conversion and cure rates in retreatment smear positive pulmonary tuberculosis patients. **METHODS:** A prospective study which included one hundred and twenty four smear positive retreatment pulmonary tuberculosis patients. Baseline data from patients was collected. Subsequent follow up was done at 3rd, 4th, 5th, 6th, 8th and 9th month. On follow up repeat sputum sample was taken and patients were assessed for sputum conversion and cure rate. **RESULTS:** The most affected group was 45-54(29.8%) years, followed by 35-44yrs (27.4%). The overall sputum conversion rate at the end of 3rd /4th month was 55.6%. The cure rate for patients with sputum 3+, 2+, 1+ were 33.96%, 22.64% and 37.74% respectively. There is no association between outcome and sputum grading ($p=0.607$). The overall cure rate was 42.7% and the default rate was 33.04%. The failure rate was 12.09% and the death rate was 11.29%. The commonest cause for default was illiteracy, smoking and alcohol intake. **CONCLUSION:** Patient education and counseling regarding the importance of giving up addictions, providing drugs to the doorsteps, involving family members in the treatment and treating failure group of patients with appropriate drugs based on DST will improve cure rates and reduce default rates.

KEYWORDS: Directly observed Treatment, Short Course (DOTS), Revised National Tuberculosis Control Programme (RNTCP), Human immune deficiency virus (HIV).

INTRODUCTION: One of the greatest challenges facing health care systems at the dawn of the 21st century is the fight against tuberculosis. In 1990 the World Health Organization (WHO) report on the Global Burden of Disease ranked TB as the seventh most morbidity-causing disease in the world, and expected it to continue in the same position up to 2020. Worldwide statistics are staggering. In 2001, the WHO estimated that 1.86 billion persons were infected with tuberculosis. Each year, 8.74 million develop tuberculosis and nearly 2 million die. This means that someone somewhere contracts TB every four seconds and one of them dies every 10 seconds.⁽¹⁾ The number of TB cases in the country has increased since 1983, mainly due to HIV/AIDS. The global community woke up to this disease in 1993, when WHO declared TB as a global emergency.

Directly Observed Treatment, Short Course (DOTS) is a brand name of the World Health Organization (WHO), recommended as TB control strategy. It is vital for the success of TB control that the health care workers should treat TB patients within this framework of Revised National Tuberculosis Control Programme (RNTCP).

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In India, the Revised National Tuberculosis Control Program (RNTCP) standardizes the care of all patients with tuberculosis, nationwide. This RNTCP uses the DOTS strategy, which is based on results of tuberculosis research done in India. The “DOTS strategy” is the globally accepted standard for diagnosis and treatment of tuberculosis.⁽²⁾ The Objectives of RNTCP are to achieve and maintain at least 85% cure rate of new sputum smear positive patients and to achieve and maintain detection of at least 70% of such cases in the population.⁽²⁾

Tuberculosis can be controlled only with EFFECTIVE SUPERVISION and GOOD PROGRAMME MANAGEMENT. A poorly managed TB control programme can worsen the epidemiological situation of TB in a community. However, directly observed treatment (DOT) is not just supervised swallowing but a service to the patient. With short course chemotherapy it is easier to prevent drug resistance by using directly observed treatment, and achieve high cure rates.⁽²⁾

To evaluate the DOTS strategy and its outcome in Retreatment smear positive patients (CATEGORY II) under RNTCP is the purpose of this study.

The RNTCP category II consists of a heterogeneous group of patients, most of whom are smear-positive retreatment cases. Relapse and failure after category I, and treatment after default (TAD) are the different subgroups that comprise the smear-positive retreatment group. These subgroups are different bacteriologically and pathogenetically. However, all these patients are treated with the same regimen (category II) under the program.

OBJECTIVES OF THE STUDY:

1. To evaluate favourable/ unfavourable outcome in different groups such as relapse, failure and treatment after default.
2. To compare grades of sputum positivity and outcome.
3. To evaluate interval of sputum conversion in all groups.
4. To study the possible causes for unfavourable outcome.

MATERIALS AND METHODS: The source of data for the study was collected from patients attending a rural health centre in Karnataka and also from District Tuberculosis Centre.

METHOD OF COLLECTION OF DATA: All patients attending: All patients satisfying the inclusion and exclusion criteria will be included in the study. Satisfying the inclusion and exclusion criteria will be taken for the study.

A prospective study including one hundred and twenty four microscopically proven cases of sputum smear positive retreatment pulmonary tuberculosis from Dec 2013 to April 2015.

A semi structured, pretested proforma is filled by interviewing the patients and clinical examinations are done by the investigator himself. Once baseline data from patients is collected, then, subsequent follow up is done in the 3rd, 4th, 5th, 6th, 8th and 9th month. Total duration of follow up is for 9 months. Total duration of study is one and half years.

DATA ANALYSIS: Descriptive statistics such as mean, SD and proportion was used to present the data. Chi-square test was used to find out the relationship between categorical variables and t-test was used to compare the continuous variables.

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Pearson's correlation coefficient was used to examine the correlation between continuous variables. A two-tailed p-value considered as significant and 0.01 as highly significant. Data analysis was done using SPSS v16.0 software.

Inclusion Criteria:

1. Defaulters of DOTS regimen.
2. Treatment failure patients of DOTS regimen.
3. Relapse cases of Tuberculosis.

Exclusion Criteria:

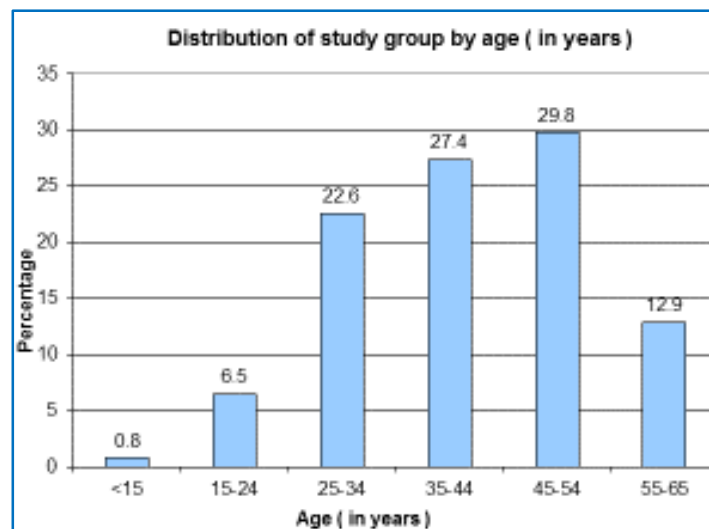
1. All patients with no previous history of pulmonary or extra pulmonary tuberculosis including newly detected sputum positive tuberculosis patients or who has taken anti tuberculosis treatment for less than a month.
2. Patients with HIV POSITIVE.
3. Patients with Diabetes mellitus.
4. Patients not willing for the study.

RESULTS AND ANALYSIS:

Age (in years)	Frequency	Percent
<15	1	0.8
15-24	8	6.5
25-34	28	22.6
35-44	34	27.4
45-54	37	29.8
55-65	16	12.9
Total	124	100.0

Table 1: Distribution of study group with age

Predominant age group in our study was 45-54yrs (29.8%), patients with age <15 yrs constituted the least number (0.8%).

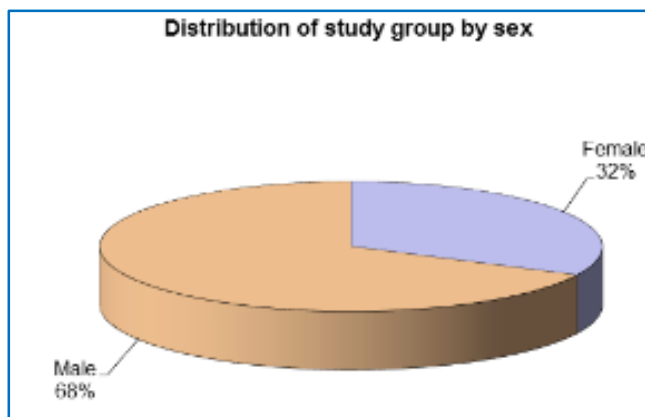


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Sex	Frequency	Percent
Female	40	32.3
Male	84	67.7
Total	124	100.0

Table 2: Distribution of study group with sex

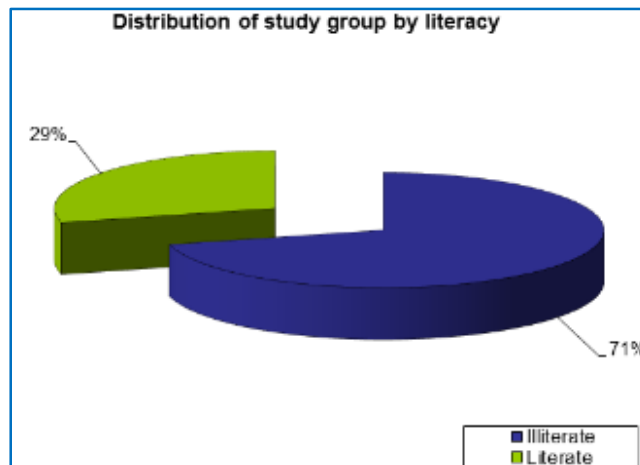
67.7% of our study group was male sex and females constituted the rest.



Literacy	Frequency	Percent
Illiterate	88	71
Literate	36	29
Total	124	100.0

Table 3: Distribution of study group by literacy

In our study, 71% of the patients were illiterates and the rest were literates.

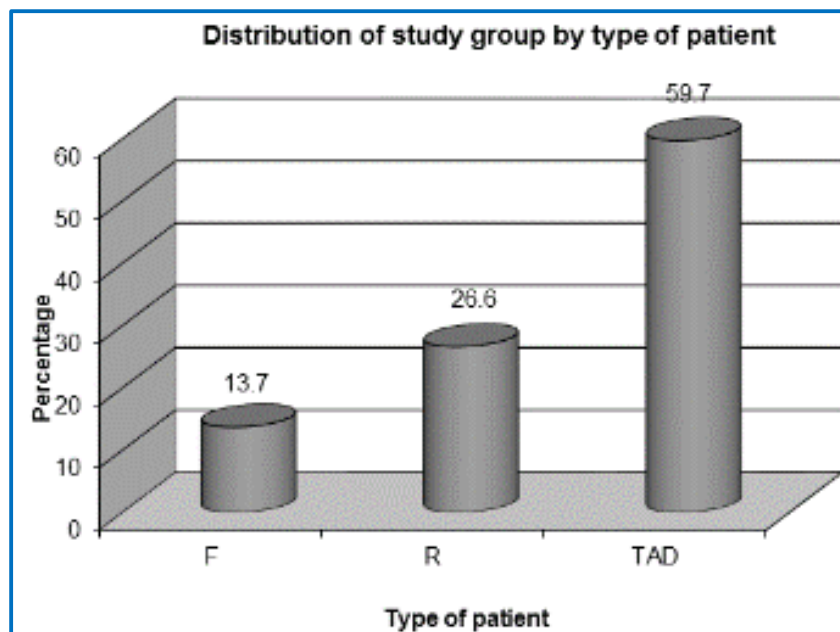


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Type of patient	Frequency	Percent
F	17	13.7
R	33	26.6
TAD	74	59.7
Total	124	100.0

Table 4: Distribution of study group by type of patient

Majority of the patients in our study belonged to TAD group (59.7%), failure group was the least in number (13.7%).

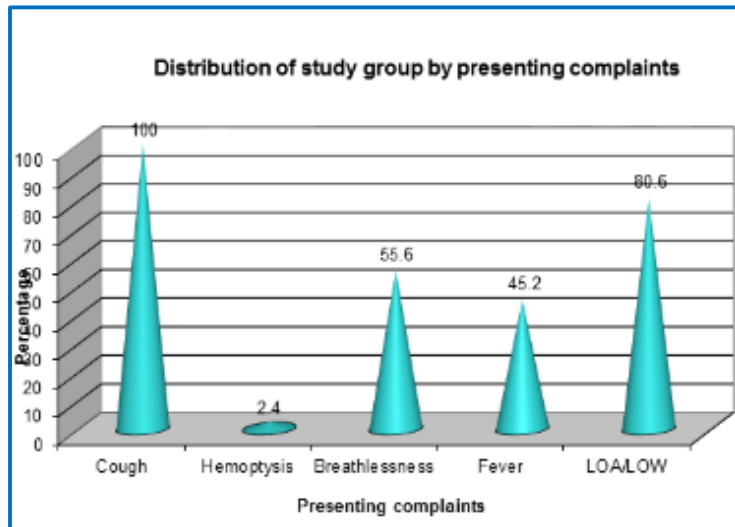


Presenting complaints	Frequency	Percent
Cough	124	100
Hemoptysis	3	2.4
Breathlessness	69	55.6
Fever	56	45.2
LOA/LOW	100	80.6

Table 5: Distribution of study group by presenting complaints

Almost all the patients in the study had cough (100%) as a predominant symptom and around 80% of patients had constitutional symptoms like LOA/LOW, half of them had breathlessness of different grades and fever was present in 45%.

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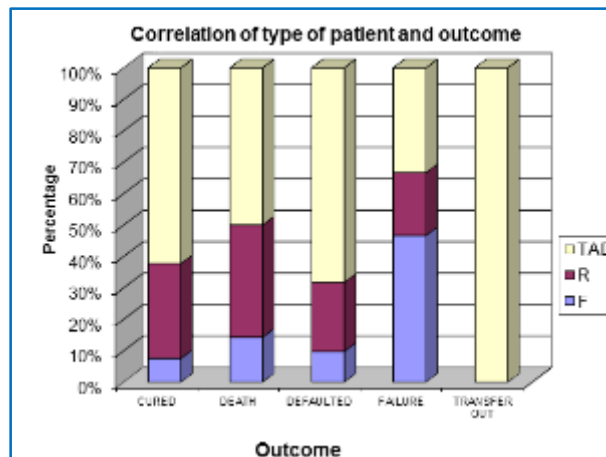


Outcome	Type of patient			Total (%)
	F (%)	R (%)	TAD (%)	
Cured	4(7.5)	16(30.2)	33(62.3)	53
Death	2(14.3)	5(35.7)	7(50)	14
Defaulted	4(9.8)	9(22)	28(68.3)	41
Failure	7(46.7)	3(20)	5(33.3)	15
Transfer out	0	0	1(100)	1
Total	17	33	74	124

Table 6: Correlation of type of patient and outcome

$\chi^2 = 6.230$, $df=2$, $p=0.044$, Significant.

There is statistically significant association between type of patient and outcome ($p=0.044$). Cured patients more observed in TAD group (62.3%) than in other groups. Default (68.3%) and deaths (50%) were higher in TAD group of patients.



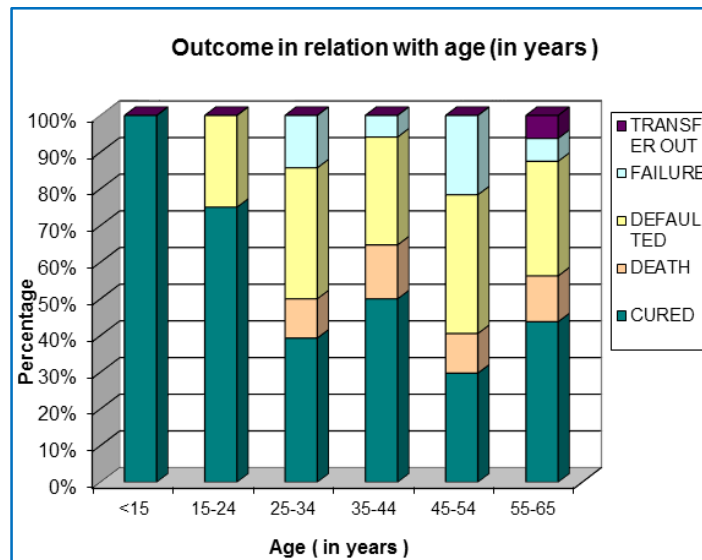
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Age	Cured (%)	Death (%)	Defaulted (%)	Failure (%)	Transfer Out (%)	Total
<15	1(100)	0	0	0	0	1
15-24	6(75)	0	2(25)	0	0	8
25-34	11(39.3)	3(10.7)	10(35.7)	4(14.3)	0	28
35-44	17(50)	5(14.7)	10(29.4)	2(5.9)	0	34
45-54	11(29.7)	4(10.8)	14(37.8)	8(21.6)	0	37
55-65	7(43.75)	2(12.5)	5(31.25)	1(6.25)	1(6.25)	16
Total	53	14	41	15	1	124

Table 7: Outcome in relation with age

$\chi^2 = 4.439$, $df=3$, $p=0.218$, Not significant.

There is no association between outcome and age ($p=0.218$). Most of the cured patients were seen in the age group <15 years (100%) and 15-24 years (75%) followed by in 35-44 years (50%) and 55-65 years (43.75%) whereas Failure (21.6%) and defaulted patients (37.8%) were more seen in the age group 45-54 years.



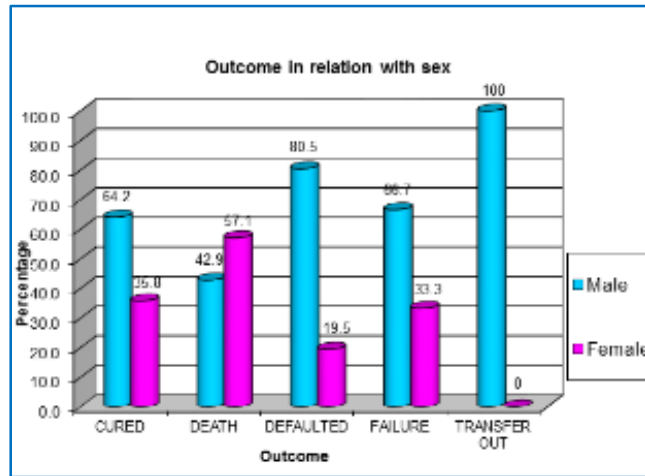
OUTCOME	Sex		Total
	Male (%)	Female (%)	
CURED	34(64.2)	19(35.8)	53
DEATH	6(42.9)	8(57.1)	14
DEFAULTED	33(80.5)	8(19.5)	41
FAILURE	10(66.7)	5(33.3)	15
TRANSFER OUT	1(100)	0	1
Total	84	40	124

Table 8: Outcome in relation with sex

$\chi^2 = 0.702$, $df=2$, $p=0.704$, Not significant.

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There is no association between sex and outcome ($p=0.704$). Cured patients more observed in Male patients (64.2%) than females (35.8%) whereas more defaulted is found in Males (80.5%) followed by failure (66.7%).

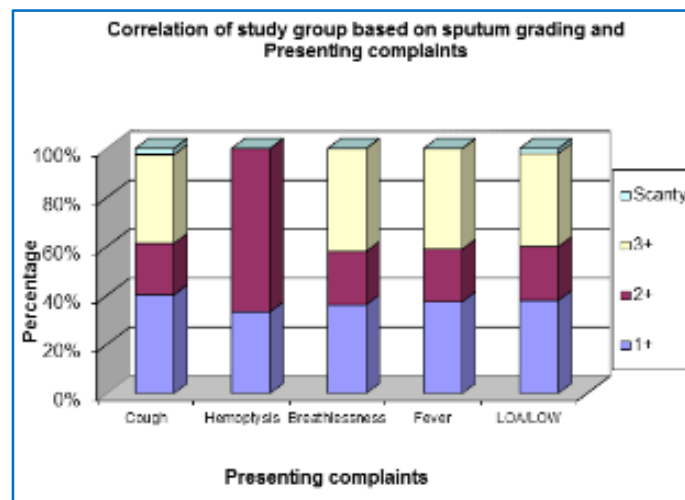


Presenting complaints	Sputum grading			Scanty	Total
	1+(%)	2+(%)	3+(%)		
Cough	50(40.32)	26(20.97)	45(36.29)	3(2.42)	124
Hemoptysis	1(33.3)	2(66.7)	0	0	3
Breathlessness	25(36.23)	15(21.74)	29(42.03)	0	69
Fever	21(37.5)	12(21.43)	23(41.07)	0	56
LOA/LOW	38(38)	22(22)	38(38)	2(2)	100

Table 9: Correlation of study group based on sputum grading [sputum(PT)] and presenting complaints

$$\chi^2 = 0.659, df=6, p=0.995.$$

There is no association between presenting complaints and sputum grading ($p=0.995$).



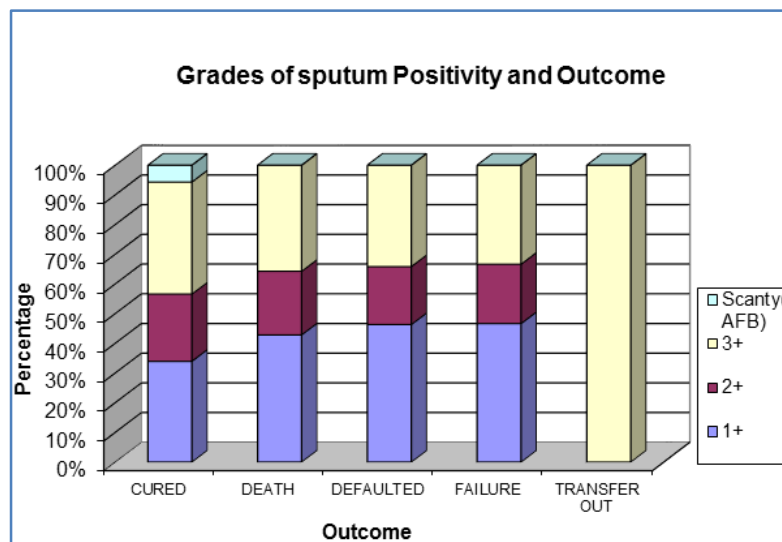
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OUTCOME	Sputum grading				Total
	1+(%)	2+(%)	3+(%)	Scanty (AFB)(%)	
CURED	18(33.96)	12(22.64)	20(37.74)	3(5.66)	53
DEATH	6(42.86)	3(21.43)	5(35.71)	0	14
DEFAULTED	19(46.34)	8(19.51)	14(34.15)	0	41
FAILURE	7(46.67)	3(20)	5(33.33)	0	15
TRANSFER OUT	0	0	1(100)	0	1
Total	50	26	45	3	124

Table 10: Grades of sputum Positivity and Outcome

$$\chi^2 = 0.999, df=2, p=0.607$$

There is no association between outcome and sputum grading ($p=0.607$). Cured patients (37.74%) more observed in 3+ grade whereas defaulted patients were more in grade 1+ (46.34%).



Sputum status	Sputum grading				Total (%)
	1+(%)	2+(%)	3+(%)	Scanty (%)	
Pre-treatment	50	26	45	3	124
3 rd / 4 th month	27(54)	12(46.2)	27(60)	3(100)	69(55.6)
5 th / 6 th month	28(56)	12(46.2)	28(62.2)	3(100)	71(57.3)
8 th / 9 th month	29(58)	12(46.2)	28(62.2)	3(100)	72(58.1)

Table 11: Follow up sputum status at the end of 3, 4, 5, 6, 8 and 9th month with sputum grade

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No. of sputum smearpositive converted to sputum smear negative at the End of intensive phase

$$\text{Sputum Conversion Rate} = \frac{\text{No. of sputum smearpositive converted to sputum smear negative at the End of intensive phase}}{\text{Total no. of sputum smears positive patients initiated on treatment}} \times 100$$

$$= \frac{53}{124} \times 100$$

Cure rate = $\frac{\text{No of cured patients}}{\text{No of patients initiated on treatment}} \times 100$

Cure rate = $53 / 124 * 100 = 42.7 \%$

Follow up sputum status as per sputum Grading:

- Sputum conversion rates for 1+ is 54%
- Sputum conversion rates for 2+ is 46.2%
- Sputum conversion rates for 3+ is 60%
- Sputum conversion rates for scanty is 100%

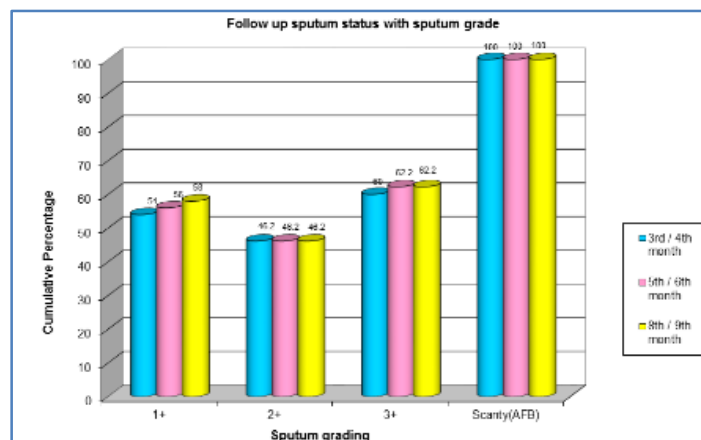


Fig. 11.1

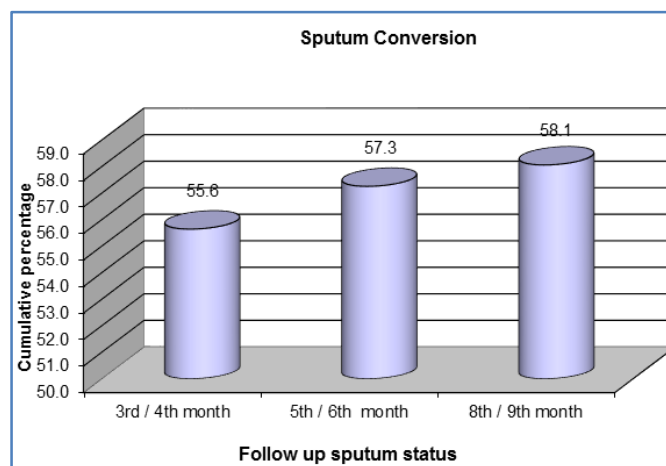


Fig. 11.2

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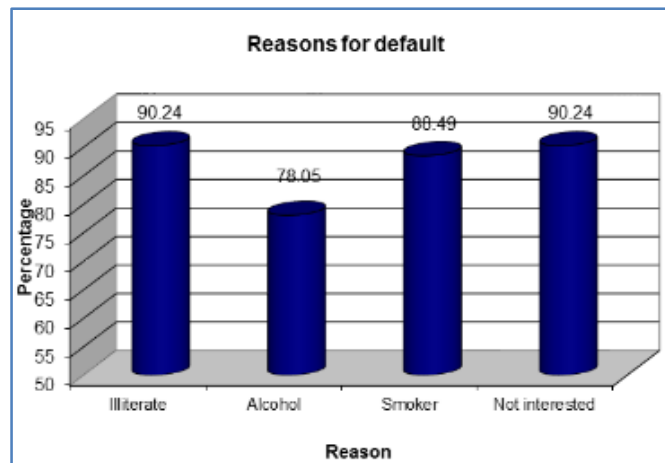
Sputum conversion rates at the end of Intensive Phase (3rd /4th month) were 55.6%.

Sputum conversion rate at the end of mid continuation Phase (5th /6th month) was 57.3% and 58.1% at the end of treatment.

Reasons for default (n=41)	Frequency	Percent
Illiterate	37	90.24
Alcohol	32	78.05
Smoker	33	88.49
Not interested	37	90.24
Failure rate (n=17)	Frequency	Percent
Illiterate	15	88.24
Alcohol	11	64.71
Smoker	10	58.82
Not interested	15	88.24

Table 12: Reasons for default and failure rates

Smoker, illiterates and alcoholic had higher default rates compared to their counterparts, failure rates were also found to be high in these group of patients.



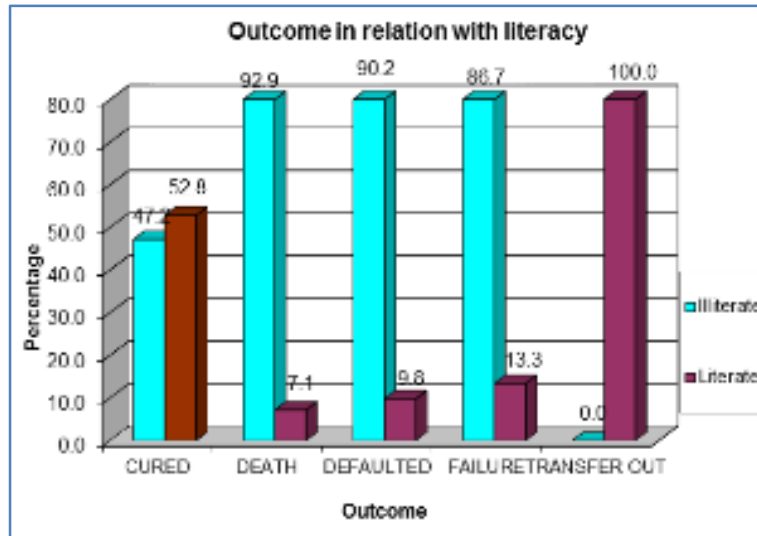
Outcome	Literacy		Total
	Illiterate (%)	Literate (%)	
Cured	25(47.2)	28(52.8)	53
Death	13(92.9)	1(7.1)	14
Defaulted	37(90.2)	4(9.8)	41
Failure	13(86.7)	2(13.3)	15
Transfer out	0	1(100)	1
Total	88	36	124

Table 13: Outcome in relation with literacy

$\chi^2 = 25.78$, $df=2$, $p<0.0001$.

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There is statistically significant association between literacy and outcome ($p < 0.0001$). Cured patients were more observed in literates (52.8%) than illiterates (47.2%) whereas deaths were observed more in illiterates (92.9%) than literates (7.1%). Failures more seen in illiterates (86.7%) than literates (13.3%).



	Weight at the time of presentation	Weight at the end of treatment
Mean	39.58	42.31
SD	6.974	7.716

Table 14a: Correlation of weight of the patient at the time of presentation and at the end of the treatment

Correlation coefficient (r)	0.905
p-value	0.01

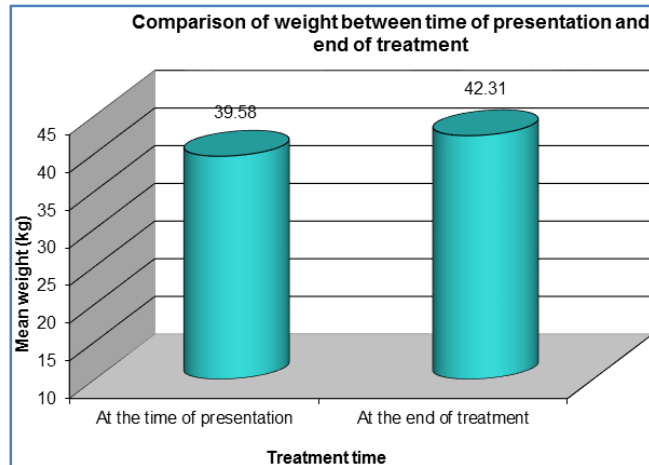
Table 14b

	At the time of presentation	At the end of treatment	t-value	p-value
Weight (kg)	39.58 ± 6.974	42.31 ± 7.716	2.83	0.005

Table 14c: Comparison of weight between time of presentation and end of treatment

There is statistically significant ($p < 0.005$) gain in the weight at the end of treatment (42.31 ± 7.716) compared to at the time of presentation (39.58 ± 6.974).

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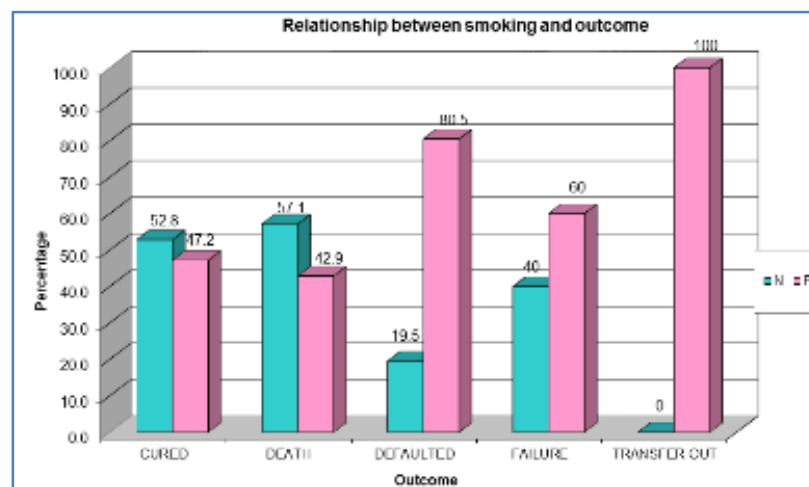


Outcome	Smoking		Total
	N (%)	P (%)	
Cured	28(52.8)	25(47.2)	53
Death	8(57.1)	6(42.9)	14
Defaulted	8(19.5)	33(80.5)	41
Failure	6(40)	9(60)	15
Transfer out	0	1(100)	1
Total	50	74	124

Table 15: Relationship between smoking and outcome

$\chi^2 = 6.644$, $df=2$, $p=0.036$.

There is statistical significant association between smoking and outcome ($p=0.036$). Cured patients more observed in non-smokers (52.8%) than smokers (47.2%). Defaulted more seen in smokers (80.5%) than non-smokers (19.5%).



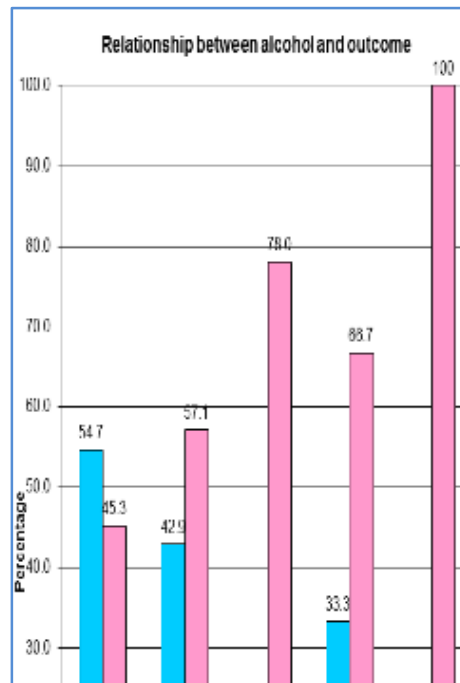
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Outcome	Alcohol		Total
	N (%)	P (%)	
CURED	29(54.7)	24(45.3)	53
DEATH	6(42.9)	8(57.1)	14
DEFAULTED	9(22)	32(78)	41
FAILURE	5(33.3)	10(66.7)	15
TRANSFER OUT	0	1(100)	1
Total	49	75	124

Table 16: Relationship between alcohol and outcome

$$\chi^2 = 9.218, df=2, p=0.01.$$

There is statistically significant association between alcohol and outcome ($p=0.01$). Failure patients more observed in alcoholics (66.7%) than non-alcoholics (33.3%). Defaults more seen in alcoholics (78%) than non-alcoholics (22%).



DISCUSSION: The current study is a prospective study which included one hundred and twenty four cases of Retreatment sputum smear positive pulmonary tuberculosis. Baseline data from patients was collected, subsequent follow up was done at 3rd, 4th, 5th, 6th, 8th and 9th month which includes extended intensive phase.

The outcomes were categorized as: those cured, treatment failure, defaulters, transfer out and death. Cured patients were those who were sputum smear positive before commencement of treatment and then subsequently confirmed to be sputum negative at 8th (or 9th) months and on at least one previous occasion. Treatment failure included patients who remained sputum smear positive at 5 months or later during treatment.

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Patients who failed to collect medication for more than 2 consecutive months during the course of treatment were classified as defaulters. Patients were assessed for interval of sputum conversion and cure rates in these subgroups of retreatment smear positive patients under RNTCP.

AGE AND SEX: Age: In the current study the Majority was in between 45-54 years (29.8%) followed by 35-44 (27.4%) and 25-34 (22.6%) years group.

Male (67.7%) patients showed higher incidence of tuberculosis when compared to female patients (32.3%).

In a comparative study done by RNTCP⁽³⁾ in 2005, patients in the age group 25-34 accounted for the maximum number showing sputum positivity for tuberculous bacilli. The study by Chan-yeunget al⁽⁴⁾ also showed male (69.1%) preponderance.

Kelly E Dooley et al⁽⁵⁾ In their study, of retreatment patients out of 291 patients, 272 were registered among them of which 78% were men and the study group was in the mean age group of⁽³⁾ 7yrs.

Type of Patients: In this study, out of 124 patients, TAD were 74(59.7%), Relapse 33(26.6%) and failure were 17(13.7%).

In another study Mukherjee et al,⁽⁶⁾ Out of the total 234 patients, 148(63.24%) were classified as relapse, 52(22.22%) were failure, and 34(14.52%) were TAD.

T. Sevim, G. Ataçet al⁽⁷⁾ in their study of total 57 retreatment patients (TAD-35.1%, Relapse-64.9%).

Retreatment patients is contributed more by relapses in other studies whereas in the present study TAD patients are more in number than relapses.

Follow up of Sputum Status: In the present study, with pretreatment sputum grading of 1+, 2+ and 3+ the sputum conversion rates at the end of Intensive phase(3rd /4th month) were 54%, 46% and 60% respectively with all three cases of scanty grade going in for conversion at the end of Intensive phase (100%). Out of 124 patients, the sputum conversion rates at the end of 3rd /4th month in all smear positive patients were 55.6%. Overall cure rates among the present study group was 42.7% with the default rate 33.04%, failure rate 12.09% and the death rate was 11.29%.

In another study by Joseph N et al,⁽⁸⁾ Of 286 tuberculosis patients, 74.1% were on Category I treatment. The sputum conversion rate among Category I and II patients was 91.5% and 73% respectively. Category I patients showed a cure rate of 77.4%, a default rate of 7.5% and a failure rate of 15.1%. Category II patients showed a cure rate of 47.3%, default rate of 20.3% and failure rate of 32.4%.

Sputum Grading as Predictor of Treatment Outcome: In our study, the cure rate for patients with sputum 3+, 2+, 1+ were 33.96%, 22.64% and 37.74% respectively. There is no association between outcome and sputum grading ($p=0.607$). Cured patients (37.74%) more observed in 3+ grade whereas in defaulted patients observed more in grade 1+(46.34%).

Mukherjee A et al⁶, The overall cure rate was greater for those with low-grade sputum (76.54%), compared with high-grade sputum positivity (65.33%); while the incidence of patients not cured on therapy was higher in the high-grade sputum positivity group. A favorable outcome was more likely in lower grades of sputum positive cases in all three Groups.

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Whereas the study by Rajpal et al,⁽⁹⁾ showed 85% cure rate for sputum 3+ and 97.7% for the rest of the patients (combined graded sputum scanty, 1+ and 2+).

The study by Singla et al¹⁰ showed a cure rate of sputum 3+ was 76% and sputum 1+, 2+ scanty was 85%.

In our study, failure rate for sputum scanty 1+, 2+ and sputum 3+ were 46.67%, 20% and 33.33% respectively when compared to study by Singla et al which showed that the default rate should be less than 10%. The failure rate was 9.1% and death resulted in 1.8 %cases.

However Nateniyane et al,⁽¹¹⁾ reported that 68.7% were cured, 17.6% died, 10.6% were transferred out and 2.6% were treatment failures. The reasons for low cure rate were HIV co-infection and high number of transfer rates in their study. The cure rate was 76% and default rate was 15% in the study conducted by Chandrashekar et al.⁽¹²⁾

Outcome Based on type of Patient: In the present study, There is statistically significant association between type of patient and outcome ($p=0.044$). Cured patients more observed in TAD group (62.3%) than in other groups. There is only one patient transfer out of TAD patient. Default (68.3%) and deaths (50%) were higher in TAD group of patients. Also failure rates are high in treatment failure group with outcome of 88.24% failure.

In a study by Mukherjee A et al,⁽⁶⁾ the differences were statistically significant ($p < 0.05$) when compared between relapse versus failure ($Z = 2.88, p = 0.001$) and relapse versus default ($Z=2.20, p=0.01$). Among unfavorable outcomes, chronic cases were more likely to be in the failure group (26.92%), followed by treatment after default (23.53%) and relapse (6.08%), with a significant difference between relapse and failure ($Z=1.81, p=0.03$). The default rate was higher among the failure group (15.38%), while deaths were higher in TAD (8.82%).

R. K. Mehra et al¹³ in their study out of 442 relapse cases, 405(91.6%) could be followed-up and 390 were again treated with cat II RNTCP regimen. Of these, 298(76.4%) had a successful outcome.

And Out of 190 failure cases from cat I regimen only 127 were re-registered for retreatment with successful outcome of 48.8%.

In contrast, the success results for 2006 cohorts as reported by RNTCP performance reports were 72.5% and 55.7% for relapse and failure groups respectively.

Kelly E Dooley et al⁵ in his study of retreatment patients, Retreatment was successful in 173 (74%) of relapse patients, 10(48%) of failure patients, and 15 (41%) of default patients. ($p < 0.01$).

E Heldalet al¹⁴ in his study concluded that the retreatment failure rate in 'treatment after failure' patients was significantly higher than in retreatment after relapse or default in both periods.

J. C. Saravia et al¹⁵ compared two retreatment strategies in Category I failures. Strategy A is standard retreatment regimen and Strategy B with second line drugs after DST results. Strategy B was three times more likely than Strategy A to cure patients (79% vs. 38%, RR 5 2.9, 95% CI 1.7–5.1) and five times more likely to cure patients than the Category II regimen alone (79% vs. 15%, RR 5.2, 95%CI 3.0–9.2). Strategy B also significantly reduced delays to MDR-TB diagnosis and to the initiation of MDR-TB therapy. A retreatment strategy based on DST and eliminating the Category II regimen can improve clinical outcomes among Category I treatment failures found to have active, infectious MDR-TB.

Afranio L. Kritski et al¹⁶ in their Study assessed factors associated with adverse outcomes and drug resistance in Retreatment patients. Out of 206 patients, relapses of 37(18%) and failures of

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91(44%for 1st line), 78 (38% for 2nd line) with mean age of 42yrs (19-79 yrs) showed a cure of 51%, 30% abandoned the treatment, 13% died and 3% were treatment failures.

Reason for Default: In our study, the commonest reasons for default were alcohol intake, substance abuse and illiteracy which go with Chandrashekar et al⁽¹²⁾ who reported illiteracy, alcohol intake & smoking as the causes for default. The study by Tekle et al⁽¹⁷⁾ reported that default rate was 11.3%, the reason being lack of family support, inadequate knowledge of treatment duration and side-effects of medication.

Risk Factors for Default: In the current study more number of defaults were seen in age group of 45-54yrs (37.8%), male sex (80.5%), those who were TAD type of patient (68.3%), illiterates (90.24%), alcoholics (78.05%), smokers (88.5%) and those who were not interested (90.24%).

In a similar study done by Kelly E Dooley et al⁽⁵⁾ quoted the risk factors for treatment default which included male sex, substance use, missed doses during the intensive phase, and hospitalization.

In a study done to evaluate the risk factors for default of patients put on DOTS treatment during 1997-2003, Out of 774 patients there were 178(23%) defaulted, the rate was highest (78%) during the continuation phase of the treatment. HIV positive patients had twice the risk than HIV negative. Noncompliance was highest in male sex ($p<0.001$) with previous treatment ($p>0.005$), sputum smear status ($p>0.005$) were not significantly associated with defaults from treatment, by O J Daniel et al.⁽¹⁸⁾

OUTCOME:

1. Sex: In our study it was found that Cured patients more observed in Male patients (64.2%) than female patients (35.8%) whereas more defaulters found in Male (80.5%) followed by failure (66.7%).
2. Reports by Chandrashekar et al⁽¹²⁾ also showed higher incidence of default in males (13.8%) in comparison to females (5%).
3. Literacy: In the present study, cured patients more observed in literates (52.8%) than illiterates (47.2%) whereas death observed more in illiterates (92.9%) than literates (7.1%). Failure is more seen in illiterates (86.7%) than literates (13.3%). Defaults are more seen in illiterates (90.2%) than in literates (9.8%). In the study conducted by Chandrashekar et al⁽¹²⁾ the default rate in the illiterate is more (12.7%) when compared to the literate (7.9%).
4. Alcohol: In our study, it is evident that Failure patients more observed in alcoholic (66.7%) than non-alcoholic (33.3%). Defaulted more seen in alcoholic 78% than non-alcoholic (22%). In the current study, There is statistical significant association between smoking and outcome ($p=0.036$). Cured patients more observed in non-smokers (52.8%) than smokers (47.2%). Defaulted more seen in smokers (80.5%) than non-smokers (19.5%). Chandrashekar et al⁽¹²⁾ also reported a higher default rate in alcoholics (17.1%) than non-alcoholics (6%).

CONCLUSION: In rural areas of the developing world as in India, where there is a heavy burden of TB and limited resources, it is not possible to perform culture and sensitivity for all retreatment cases under the present program conditions as their number is high.

Therefore we propose that after excluding the relapse and TAD cases that have a favorable response on standard retreatment regimen, culture and sensitivity followed by treatment with sensitive second line drugs be reserved for those patients in the failure sub group.

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To prevent the increasing percentage of retreatment smear positive patients more efforts to be Executed to:

1. Educate the patient regarding the diseases and the course of the treatment.
2. Take the help of family members for drug adherence.
3. Closely look for possible drug adverse reactions.
4. Motivate to give up addictions.

Delivery of Anti tubercular drugs to patient`s doorstep would be financially more viable as the patient would be saving transportation expenditure and avoiding loss of daily wages. Extra effort such as supervision, counseling and home visits to motivate those patients likely to default during the initial phase and returning them to treatment would have ensured a favorable treatment outcome.

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