

Original Article

SPUTUM SMEAR CONVERSION DURING AN ALTERNATIVE METHOD FOR PROVIDING "DIRECTLY OBSERVED THERAPY SHORT COURSE" IN A RURAL SETUP THROUGH MOBILE TEAM

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ABSTRACT

Background: Tuberculosis is a disease as old as the history of mankind. Nothing substantial could be done by the National Tuberculosis Control Program, launched in our country about 6 decades back. According to a report in India, only 30% TB cases are diagnosed and of them only 35% take treatment for adequate duration. This study was conducted to know sputum conversion of supervised short course chemotherapy for pulmonary tuberculosis.

Methods: The study was carried out on rural patients of Bareilly district. The patients were divided in two groups. Group A received drugs under supervision and Group B took conventional domiciliary treatment. In this study supervision was done by a 'designated' person who was usually parents, spouse, sibling or children and if no one was available or not found intelligent enough to do this job, a friend of patient living in the village was considered.

Result: The sputum conversion was significantly faster in group A as compared to group B; but at 10th week the difference between the two groups became non-significant. The significance was further lost at 3 months, as 100% patients in both groups converted to negative and remained sputum negative at the end of 6 months.

Conclusion: The sputum conversion was significantly faster in patient received anti-tuberculosis drugs under supervision as compared to patient who took conventional domiciliary treatment. The present study further supports the fact that DOTS with daily supervision is an effective treatment for tuberculosis.

Keywords: sputum, short course chemotherapy, ATT, pulmonary tuberculosis

INTRODUCTION

Tuberculosis is a disease as old as the history of mankind. It still remains a worldwide public health problem; almost one third of world population is affected by tuberculosis infection. It has also become the main killer of adults aged 15-59 years which happen to be the main productive and reproductive years of life. TB accounts for 17.6% of all deaths from communicable disease, and for 3.5% of all cause-mortality¹, in India despite the fact that the causative agent was discovered more than 100 years ago and highly effective drugs and vaccines are available for decades now.

Nothing substantial could be done by the National Tuberculosis Control Program which was launched in our country about 6 decades back. According to a report in our country out of all the cases of TB, only 30%

are diagnosed and of them only 35% take treatment for adequate duration and only 75% are cured with this conventional chemotherapy. Thus out of 100 cases of TB only 8 Cases are finally cured².

In 1993, the government of India decided to give a new thrust to TB control activities by revitalizing the NTP, with the assistance from international agencies. The Revised National TB Control Programme (RNTCP) thus formulated, adopted the internationally recommended Directly Observed Treatment Short-course strategy, as the most systematic and cost effective approach to revitalize the TB control programme in India. With all these consideration this study has been planned to evaluate sputum smear conversion during an alternative method for providing "directly observed therapy short course" in a rural setup through mobile team.

MATERIAL AND METHODS

This study comprised of patients from rural area of Bareilly district.

Inclusion Criteria: A person over 10 yrs of age and a person with untreated or fresh cases of pulmonary TB.

Exclusion Criteria: Extra pulmonary tuberculosis; Very poor general condition; Pregnancy; Concomitant diseases like diabetes, hepatic failure and dysfunction; and Death during treatment.

In this study tuberculosis cases were picked up through door to door survey of the randomly selected villages organized in the rural areas of Bareilly district. In door to door survey, survey/census card were filled up and all the houses were numbered by the social worker. The social worker filled a prescribed card of each family enumerating names, age of all the family members and chest symptoms. After census the doctor's team examined every individual having any respiratory symptoms.

Tuberculosis suspects were subjected to detailed examination in the following manner.

1. (a) Detailed history of symptoms i.e. Fever, Cough, Expectoration, Chest pain, Haemoptysis, Breathlessness, Loss of appetite, wt. loss, weakness. (b) Past history of disease, history of other diseases likes Diabetes, HTN, Jaundice, any chronic disease earlier. (c) Personal history, family history of contact. (d) History of anti-tubercular treatment. (e) Positive clinical findings were noted.

2. Routine hematological and other examination like Hb, TLC, DLC, Urine: Routine, Microscopic; Blood Sugar, S.Bilirubin, SGPT, S.Creatinine. If needed, Montoux test.

3. Sputum smear examination for AFB: First before starting treatment and thereafter every fortnightly till atleast three specimens were negative. All suspected patients of pulmonary tuberculosis were advised to bring sputum samples and ensured that the specimen given for examination has been properly expectorated and is not saliva. The staining of sputum was done by Ziehl-Neilson Method.

4. Radiological Examination: P-A view of chest was done in all tubercular suspected patients. Radiological examination was done at the starting of treatment, in between the treatment and at the end of treatment. On the basis of radiological finding pulmonary tuberculosis patients were classified as follows. (i) Minimal (ii) Moderate (iii) Far advance.

All tests were performed at institutional laboratory in Department of Pathology, Microbiology & Radiology.

After diagnosis of pulmonary tuberculosis treatment cards were filled up and patients were issued anti-tuberculous drugs fortnightly. Regimen used was 2 HRZE/4HRE (daily).

Patients were divided into two groups-both groups took same regimen of ATT.

Group - A: Patient received anti-tuberculous drugs under supervision.

Group - B: Served as control and took conventional domiciliary treatment.

In this study supervision was done by a 'designated' person who was a close relative of the patient, lived in the family or in same village. They were usually parents, spouse, sibling or children. If no one was available or not found intelligent enough to do this job, a friend of patient living in the village was considered.

The designated supervisors were passing on regular information to the investigation team. A member of our team however was instructing both groups of patients during fortnightly drug distribution in usual manner. When the patient did not turn up on scheduled date to collect drugs on respective drug distribution centre the default action was taken in both groups as follows. They were sent verbal and written reminder through other patients to collect drugs within 3 days from team's working village or base hospital. Those patients who collected their drugs within 7 days of due date stating valid reasons for their absence which in a way reflected their desire to continue treatment were not labeled as defaulters.

The reliability of the drug intake was assessed by asking a member of the family of the patients, by seeing the empty foils and vials of the drugs, by random checking of urine colour of the patients.

The patients were categorized based on their compliance and effect of regimen as follows:

Cured: Initially smear positive patients who completed treatment and had negative sputum smear result at the end of treatment.

Treatment completed: Those who took full course of treatment (6 months).

Defaulter: A patient who at any time after inclusion into the study did not collect his drugs within 7 days of due date, labeled as defaulter.

Lost cases: If they did not turn up even after the default action.

RESULTS

Since May 2012 to May 2013, 82 patients were taken from the rural area of Bareilly District. All the patients were fresh cases and sputum positive for AFB. Out of these 44 kept in Group A (Study group) and were given supervised anti-tuberculous treatment. Patients kept in Group B (Control group n= 38), were given daily unsupervised treatment.

The regimen given in both groups was 2HRZE/4HRE. In Group A 44 patients completed treatment. Initially 2 were defaulted but retrieved after default action. Whereas in Group B only 36 patients completed treatment in this group, 3 patients were defaulted out of these one was retrieved after default action and two remained defaulter.

Table 1: Distribution of patients of Group A and B according to age and sex

Age Group	Group A			Group B			Total
	M	F	Total	M	F	Total	
10-20	6	9	15	0	4	4	19
20-30	6	6	12	3	4	7	19
30-40	7	4	11	9	3	12	23
40-50	1	1	2	4	4	8	10
50-60	3	0	3	2	0	2	05
60-70	1	0	1	2	1	3	04
≥70	0	0	0	2	0	2	02
Total	24	20	44	22	16	38	82
Mean			27.95			38.73	
S.D.			12.89			15.63	

M=Male, F=Female

Table 2 Designated supervisors

	No. of patients
Parents	25 (56.8%)
Spouse	10 (22.7%)
Children	5 (11.4%)
Brother/Sister	4 (9.1%)
Friends	--
Total	44 (100%)

The effect of regimen given was seen in 44 patients in supervised chemotherapy and 36 patients in unsupervised chemotherapy. The majority of the patients in the study were between 10 - 40 years in Group A and 20 - 50 years in Group B; male to female ratio being 1.2:1. (Table 1)

Most of our patients had duration of symptoms for 5 - 8 months or less. For most of the patients, parents served as a 'designated supervisor followed by spouse. (Table 2)

All defaulters were illiterate. The treatment success rate in 44 patients of Group A was 100% at the end of treatment while in Group B 36 out of 38 (94.7%) pa-

tients completed the treatment. At the end of treatment there were no sputum smear positive in both groups. The adverse effects were almost equally distributed in both groups. (Table 3)

Table 3: Distribution of patients according to presence or absence of adverse effect of drugs

Adverse effect	Group A	Group B
Present	24 (54.5%)	20 (52.6%)
Absent	20 (45.5%)	18 (47.4%)
Total	44 (100%)	38 (100%)

Common symptoms were cough (100%), expectoration (100%), followed by breathlessness (92%), fever (85%), chest pain (71%) and loss of weight and appetite (68%) and haemoptysis (31%). Most of the patients (59.8%) were illiterate. Majority of the patients were having moderate lesion (56.9%) followed by minimal (31.7%) and, (12.2%) far advance lesions. The cavity lesions were present in 24.4% cases. Out of 82 patients, 77 (93.9%) had completed the treatment without interruption, 5 patients defaulted (6.1%). Out of 5 defaulters 3 patients were retrieved back for treatment. Two defaulters were in group A and both were retrieved back. In group B there were 3 defaulters and only 1 could be brought back to treatment. Less default and better retrieval in Group A can be attributed to role of designate supervisors. (Table 4)

The sputum conversion was significantly faster in group A as compared to unsupervised group B; but at 10th week the difference between the two groups became non-significant. The significance was further lost between two groups at 3 months, as 100% patients in both groups converted to negative. And all the patients remained sputum negative at the end of 6 months when the treatment was stopped. (Table 5)

Table 4 Distribution of patients who defaulted and retrieved

Patients category	Group A			Group B		
	Male	Female	Total	Male	Female	Total
Patients who defaulted and could be retrieved further	1	1	2	1	0	1
Patients who defaulted but could not be retrieved	0	0	0	2	0	2

Table 5: Number of patients converted from sputum positive to negative during chemotherapy in both Group A and B

Sputum conversion in weeks	Group A		Group B		Total	
	Sputum converted	Cumulative frequency (%)	Sputum Converted	Cumulative frequency (%)	Sputum converted	Cumulative Percentage
2 Weeks	0	0 (0)	0	0 (0)	0	0
4 Weeks	2	2 (4.5)	2	2 (5.5)	4	5.0
6 Weeks	18	20 (40.9)	20	22 (55.5)	38	47.5
8 Weeks	35	55 (79.5)	27	49 (75.0)	62	77.5
10 Weeks	39	94 (88.6)	34	83 (94.4)	73	91.25
12 Weeks	44	138 (100.0)	36	119 (100.0)	80	100.0

DISCUSSION

The present study compares the result of daily regimen (2RHZE/4RHE) given either with 'modified daily supervision' or unsupervised daily regimen. Both

these groups were in a way also supervised once in a fortnight at the time of drug distribution which was done very close to their houses.

A total of 82, freshly diagnosed, sputum positive and untreated patients of pulmonary tuberculosis cases were studied. Mean age was 32.92 + 15.20 years. In our study, male-female ratio was 1.2:1, 56.1% male and 43.9% female. Barnes³ in his study in 1973 and Patel et al⁴ in 2011 also found a higher incidence in males than females.

No role of literacy on default as well as on awareness was observed by Geeta K et al². In this study the default rate was almost same in both groups but in Group A all the patients who defaulted were retrieved by the efforts of 'designated supervisor' while in Group B one patient could be retrieved and two patients remained defaulted i.e. 8%. Both were males and illiterate.

Wang Jui Sui et. al⁵ studied programme which was based on W.H.O. Directly observed therapy short course, the cure rate increased from 52.2% to 95.0%. Default rate decreased from 9.3% to 0.7%.

Zhouxian Wang⁶ focussing on training one family member of patients as supervisor of drug intake and emphasized dual compliance of medical agents and patients. Cohort analysis demonstrated cure was 85.5% in 1992 to 90.4% in 1993.

A Marrero et. al⁷ in their study found 85% cured, 1.9% treatment failure, 1.9% defaulter. In 1995 Bui thi Mai et al⁸ in Hanoi found 93.9% patients completed treatment and 1.44% defaulted. The study was based on DOTS therapy.

Nehar et. al⁹ studied cure rate in Kathmandu Valley DOTS biweekly regimen which showed 89% cured, 11% defaulted, 2% died, 2% were treatment failure. Jagota P. et. Al¹⁰ studied an alternative method where supervisor were Dai, she found that 86.9% completed treatment.

In our study the results were better than various studies as shown above. However, after default action percentage of patients further rose from 93.9% to 97.6% significantly the International standard. The higher completion rate in Group A of this study was probably due to active participation of designated supervisor who ensured daily intake by patients.

One interesting fact which can be observed is that in supervised system default retrieval action was very good compared to Group B (unsupervised). The success rate in 44 patients of Group A (supervised) was 100% at the end of treatment while in Group B (unsupervised) was 36 out of 38 i.e. 94.7%. Zalesky R et. al¹¹ studied DOTS in Caucasian Countries and found after three months of treatment 93% of new smear positive patients had become smear negative.

However, in our study at 10 weeks the conversion rate of 88.6% in Group A and 94.4% in Group B were not significantly different. The significance was further lost at the end of 3 months when the conversion rate was 100% in both groups. Whereas Reider HL et al¹²

found that sputum conversion after 2 months was 75.0% (61.7 to 90.9) in refugee camp in Thailand and Laurinen et al¹³ found that 96% patients on DOTS converted from sputum positive to sputum negative in 3 months. All these findings favors our study results.

CONCLUSION

Short course chemotherapy has been proved very effective in the treatment of TB with less toxicity and greater acceptance. The present study further supports the fact that DOTS is an effective treatment for tuberculosis. It was found that in complete cure of tuberculosis, not only effectiveness of treatment regimen is important but patient compliance is also important and now with the finding of our study we are in no doubt that DOTS with daily supervision have not only the rapid sputum conversion rate but it reduces the defaulter rate also.

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