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Original Research Article

Study of the causes and factors which affect compliance of the patient in directly observed short course chemotherapy in pulmonary tuberculosis in Central India

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ABSTRACT

Background: TB is one of the most ancient diseases. World Health Organization (WHO) estimated 9.2 million new cases in 2014 out of which 2.2 million were from India. National tuberculosis programme was started since 1962 and short course chemotherapy was included in 1983. With this background in 1992 WHO and Swedish International Development Agency (SIDA) reviewed the programme. As a result, revised national tuberculosis programme (RNTCP) was started. RNTCP recommended directly observed short course chemotherapy in pulmonary tuberculosis (DOTS) and was implemented in 1993. Objective of present study was to find out the causes and factors affecting compliance of the patients in directly observed short course chemotherapy in pulmonary tuberculosis.
Methods: We studied 100 patients of pulmonary tuberculosis, who were sputum smear positive for tubercle bacilli. Patients were treated with DOTS (Directly Observed Short Course Chemotherapy) recommended by RNTCP and we observed the causes and factors responsible for interruption of the treatment in noncompliant patients.
Results: Overall compliance was 78% and 22% patients were noncompliant. Most common cause of noncompliance was side effects of drugs (12%), noncompliance was maximum (45.45%) between age group of 15-25 years. Illiterate and low socioeconomic status patients were more noncompliant 46.45% and 63.63% respectively.
Conclusions: Eventually, after seeing all merits and demerits of DOTS, we have concluded that intensive health education may have favourable impact to improve further outcome of DOTS and compliance of the patients.

Keywords: DOTS, Pulmonary tuberculosis, Revised national tuberculosis programme

INTRODUCTION

TB is one of the most ancient diseases and continues to be major public health problem of world even today. WHO reported globally 9.2 million people developed tuberculosis in 2014 and India accounts one fourth of global burden (2.2 million every year).[1]

National tuberculosis programme was started since 1962 and short course chemotherapy was included in 1983 as a pilot study by the tuberculosis research centre, Chennai, Tamil Nadu, India. with this background in 1992 who and SIDA reviewed the programme. As a result, revised national tuberculosis programme (RNTCP) was started. Initially the goal of RNTCP was to detect 70% of new smear positive cases and achieve a cure rate of 85% and in 12th five-year plan (2012-2017) the aim is early detection and treatment of at least 90% of estimated TB cases in community.[2] RNTCP recommended DOTS and was implemented in 1993. DOTS are the internationally

recommended strategy first formulated in national tuberculosis programme. WHO began to promote this programme in 1991, and in 1994 produced a framework for effective tuberculosis control that clearly described the main components of what was later known as the DOTS strategy. The framework was revised and expanded in 2002. Now this programme has reached 632 districts in 35 states and covers approximately 1 billion people across India.

METHODS

100 patients of the age ≥15 years who were sputum smear positive for tubercle bacilli were taken. Detailed history of all patient was taken and they were enquired regarding signs and symptoms of pulmonary tuberculosis. Early morning samples of sputum were collected and examined by Ziehl-Neelsen staining method. All the patients were treated with DOTS thrice weekly regimen recommended by RNTCP (Isoniazid 600mg, Rifampicin 450mg, Pyrazinamide 1500mg, Ethambutol 1200mg, thrice a week). Regular follow up with sputum smear examination was done after two months and then after completion of the treatment.

RESULTS

Overall compliance was 78% and 22% patients were noncompliant (Table 1).

Table 1: Distribution of the patients according to compliance of the treatment.

Treatment compliance	No.	%
Compliance	78	78%
Noncompliance	22	22%
<1 month	04	04%
1-2 months	14	14%
>2 months	04	04%

Table 2: Distribution of patients according to the cause of noncompliance.

Causes of noncompliance	No.	%
Side effects of antitubercular drugs	08	36.36
It was difficult to find time from work	06	27.27
I felt better hence stopped treatment	02	9.09
It was difficult to take so many pills	01	4.54
I moved away from DOT centre	01	4.54
No body accompany me to reach the centre	01	4.54
I became pregnant	01	4.54
Another doctor (quacks) told me to stop treatment	01	4.54
I did not find relief in my symptoms	01	4.54
Other	00	00

The most common cause of non-compliance was side effects of drugs (36.36%) and the major side effects were nausea and vomiting. Second common cause was difficulty to find time from work to collect the medication from DOT centre (27.27%), the third cause was that the patient felt better after a few doses and hence stopped the treatment (Table 2).

Table 3: Association of noncompliance with age and gender of patients.

Age (in years)	Male		Female	
	No.	%	No.	%
15-25	06	27.27	04	18.18
26-35	02	9.09	02	9.09
36-45	02	9.09	00	00
46-55	02	9.09	00	00
>56	02	9.09	02	9.09

Majority of non-compliant patients were between the age group 15-25years (45.45%). Non-compliance was more prevalent in males (63.63%) as compared to females (36.36%) (Table 3).

Table 4: Association of noncompliance with education.

Education status	No.	%
Illiterate	10	45.45
Primary School	02	9.09
Middle School	02	9.09
High School	02	9.09
Higher secondary School	04	18.18
Graduate	02	9.09
Post Graduate	00	00

Non-compliance was more in illiterates, 45.45 percent (Table 4) and in patients with low (class IV and V) socioeconomic status, 63.63 percent (Table 5). Maximum noncompliance was seen in housewives (45.45%) while professionals had good compliance (Table 6).

Table 5: Association of noncompliance with socioeconomic status.

Socioeconomic status	No.	%
Class I	02	9.09
Class II	02	9.09
Class III	04	18.18
Class IV	10	45.45
Class V	04	18.18

Table 6: Association of noncompliance with occupation.

Occupation	No.	%
Unemployed	02	9.09
Unskilled labourer	02	9.09
Professional	00	00
Skilled labourer	08	36.36
Housewives	10	45.45

DISCUSSION

DOTS are the proven "GOLD STANDARD" therapy for tuberculosis now a day. There are so many studies done and show high cure rates of DOTS, but there is not a single study done which shows hundred percent cure rate. There are still some hurdles present in DOTS therapy. Overall compliance in present study was 78 percent. The study results were discordant with those of Smironff M et al and Alcaide Megies J et al, which showed 85 and 91.8 percent compliance respectively with DOTS therapy.[3,4]

Twenty two percent patients were noncompliant in our study. The major cause which we have found was side effects of antitubercular drugs like nausea and vomiting (gastritis) which did not allow the patients to take the drugs regularly. The main culprit was rifampicin, so we have to take some measures to decrease or eliminate this factor as a source of noncompliance, like drug should not be taken empty stomach but again it was proved in some studies that food reduces absorption of antitubercular drugs. So, another option is prescription of antiemetics, H2 blockers or proton pump inhibitors with proper counselling of patients about the right time of drug administration along with antitubercular therapy. In our study 08 percent patients are noncompliant due to side effects of the antitubercular drugs. The study results were discordant with those of Friz P et al found 36 percent patients suffering from side effects and did not report back for treatment.[5] Burman WJ et al showed 18 percent of noncompliance with DOTS and major risk factors were alcohol abuse and homelessness.[6]

The second common cause of noncompliance was difficulty to find time from work to reach the DOT centre to collect the pill regularly. In this group, proper counselling and health education have a role as shown by Prasad R et al.[7]

The maximum number of noncompliance was in age group 15-35 years (63.63%). The reason was that, they were economically active persons in their family, so unable to spare time for regular visit to DOT centre. Noncompliance was more prevalent in males (63.63%) as compared to female (36.36%). Balasubramanian VN et al showed women were somewhat less likely than men (61% versus 76%, *P*=0.06) to receive DOT.[8]

Noncompliance was more among illiterate patients (45.45%), because these patients do not know the nature of disease and complete treatment is necessary to eliminate their disease, so as soon as they get relief they stopped treatment. Noncompliance was found to be highest in lower socioeconomic status patients because they have to go to their work thus unable to come DOT centre to collect medicines regularly. We have found maximum noncompliance amongst house wives, reason being there were no accompanying persons to get them to DOT centre.

Noncompliance has adverse consequences for individual patient as well as for community as being strongly associated with poor outcomes of therapy and transmission of tuberculosis to contacts during the period of noncompliance respectively. Although on the basis of present and some previous studies it has proved that DOTS give us very rewarding results but hundred percent cure was not achieved in any study, there are still some failures and defaulters are present in DOTS.

Another common cause of noncompliance which we have seen was interruption of treatment as soon as patient felt better. This problem occurs when patient was shifted on continuation phase as there is no provision in DOTS for proper follow up of these types of patients who have absconded from centre. So, intensive health education with proper counselling is desirable to improve efficacy of DOTS. This health education should start after preliminary assessment of patient's knowledge of tuberculosis. Education should cover the cause of disease, mode of transmission, appropriate preventive measures, common symptoms of the disease, assurance regarding effectiveness and necessity of completing the treatment without missing a single dose even after the symptoms have subsided. At each periodic visit patient should be encouraged to clear any doubts.

Decentralization of treatment to local health facilities and to the community through health staff or trained and supervised community volunteers as close to the patient's home or work place as possible and at convenient time is another helpful measure to prevent poor outcome of treatment due to long distance.

CONCLUSION

Eventually, after seeing all merits and demerits of DOTS, we have concluded that intensive health education may have favourable impact to improve further outcome of DOTS and compliance of the patients. But to find out common, commoner and commonest cause of non-compliance, study with large number of patients is needed to eliminate statistical errors and strengthen the DOTS therapy by treating these causes and factors.

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