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A STUDY ON REASON FOR MEDICATION NON-ADHERENCE IN TUBERCULOSISPATIENT AND PROPOSED CLINICAL INTERVENTIONS

Blesson Mathew*, Dona Kurian, Jibin Mathew, Aditya Senan, TR. Ashok Kumar and T. Sivakumar

Department of Pharmacy Practice, Nandha College of Pharmacy, Erode, Tamil Nadu, India.

ABSTRACT

Background: Impact of DOTS in dropping TB incidence has been restricted by non-compliance to DOTS treatment. The Identifying factors affecting compliance to TB treatment will give insights into the reasons behind high defaulter and subsequently low treatment success rates. Objective: To evaluate the reasons, why patients are non-compliant to TB treatment and thus to make recommendations, according to the findings and improve quality of life of patients. Methods: A quantitative, hospital based, prospective observational case study on default TB patients who are in TB treatment during January 2014 and June 2014 in Government Hospital Erode under RNTCP was conducted. Results: A total of 56 default TB patients from among 569 patients registered (45 males and 11 females) were interviewed. The most common reason for default arefelt better and stopped the treatment (33.92%).Other important reasons were lack of counseling (30.94%), side effects following medication (19.64%), lack of time (8.92%), fear of adverse reaction (8.92%), and lack of family support (8.92%). Conclusions: Non-compliance with anti-tuberculosis treatment is still relatively frequent and mostly associated with lack of counseling and due to fear of adverse drug reaction. With this study we are suggesting that proper monitoring of various factors that are causing patients to withdraw from TB treatment identification can play an important role in improving treatment adherence and thus improve quality of health in TB patients.

Keywords: Default, Non-Adherence, Tuberculosis, DOTS, Compliance.

INTRODUCTION

Pulmonary tuberculosis (TB) is an infectious disease caused by *Mycobacterium tuberculosis*. The pathogen was first isolated in 1882 by Robert Koch and it normallyaffects the lungs but can also employ almost any fundamental organ of the body. Untreated or uncured person with active TB will infect on the usual between 10-15 people annually2078. A person with a compromised immune system like in the case of HIV infection is at toweringrisk of becoming infected with TB. The WHO estimated that one-third of the world'spopulation is at present infected with the TB bacillus. Five to ten percent of people infectedwith TB but not infected with HIV become sick, ill or infectious in their life time. SoutheastAsia has the highest number of estimated deaths from TB but Africa has the highestmortality per capita due to the raise in HIV. The loss of life and human prospective due to TB has surged in recent years as aneffect of coinfection with HIV.¹

India is the highest TB burden and trouble country accounting for one fifth (21%) of the worldwide incidence and 9.4 million cases out of which it is estimated that 2 million cases are from India. India is 17th among 22 High Burden Countries in terms of TB incidence pace. The aim and objectives of the programme are toattain and maintain cure rate of at least 85% among New Sputum Positive (NSP) patients to reach and sustain case recognition of at least 70% of the estimated NSP cases in the community. Current focal point of the programme is on ensuring "universal access" to first-class quality early diagnosis and treatment for all TB patients from which ever supplier they choose to seek out care. Since its inception, the Programme has initiated more than 12.8 million patients on treatment, thus saving

nearly 2.3 million further lives. Since 2007,programme is achieving a treatment success rate of >85% and has constantly maintained the NSP case detection rate (CDR) of >70%.²

The Revised National TB Control Programme (RNTCP) is being implemented as a 100% Centrally Sponsored Scheme in the whole country, with Direct Observed Therapeutic Regimen (DOTS) strategy which is WHO recommended. Under the programme, diagnosis and treatment services including a supply of anti TB drugs are provided for free of cost to all TB patients. Sputum microscopy as a substitute of X-ray avoids over diagnosis and identifies infectious cases. Drugs are provided under direct observation or examination and the patients are monitored so that they complete their treatment. The programme has developed and launched "DOTS Plus" for management of drug resistance tuberculosis (DR-TB) in 2007 and has extended these services to all states and UTs across the country in 2012. The programme is currently in the process of decentralizing DOTS plus services and aims to make these services accessible in all districts by end of February 2013.³

The emergence and appearance of DR-TB presents major challenges to worldwide TB control with an increase in incident cases reaching 4, 89,000 MDR-TB cases by 2006, representing a 65% increase since 2000. Research and study has shown that failure to adhere to principles of TB control leads the development of almost all the DR-TB, and poor or non-compliance to TB treatment is the key predisposing factor for an individual to build up DR-TB. This leads to treatment failure and later may lead to death and further spread of DR-TB. Given that current treatment victory for MDR-TB is about 60%, focal point should be on preventing appearance of new DR-TB cases by ensuring appropriate management of drug-susceptible cases being infected with HIV is evidently a risk factor for developing DR-TB, most likely due to intermittent TB treatment and poor absorption of anti-TB drugs.⁴

The failure to take prescribed medication is a widespreadconfounding phenomenon. This fact must be taken into thought when one endeavor's to treat a patient or manage diseases in a community and poor adherence to a prescribed treatment increases the risk of morbidity, mortality and extend of disease in the community. The therapeutic regimens given under direct observation as suggested by WHO have been shown to be vastly effective for both preventing and treating TB but poor adherence to anti tuberculosis medication is a key barrier to its universal control. Factors related with patients for poor compliance reported in the pre-DOTS (Directly Observed Treatment Short-course) era were relief from symptoms, adverse reactions to drugs and job-related problems.⁵

Non-adherence to anti-tuberculosis treatment is defined as not approaching to the clinic for treatment for more than thirty consecutive days. It is avital barrier for controlling TB because it is associated with treatment failure, the advance of drug resistances, dissemination of the infection and bigger treatment costs. Among the possible reasons for non-compliance are, the extended duration of the treatment (6–8 months), the high number of pills (minimum of 11), adverse reactions to anti-tuberculosis medications and lack of information about the illness and its treatment.⁷

The recognition of factors that influence the possibility of discontinuing the treatment is the first step in scheming interventions that improve treatment adherence and the control of the disease. Therefore, the purpose of this study was to identify and recognize the risk factors associated with non-compliance of anti-tuberculosis.

MATERIALS AND METHODS

The study area is in Erode district of Tamil Nadu, South India. Five hundred fifty six patients registered during the study period and from that fifty six defaulters formed the study population. A quantitative, hospital based, prospective observational case series study of default TB patients who are in TB treatment during January 2014 and June 2014 in Government Hospital Erode under RNTCP was conducted.

Data collection

We obtained the list of defaulters, socio-demographic and clinical characteristics such as type of case, type of disease, and category and treatment outcome from TB Register. Treatment details such as drug regularity, number of doses taken by the patients and time of default were obtained from treatment cards. Information on patient's literacy, occupation, and personal habits like smoking and drinking were taken from patient's information form which was collected by trained social workers within 8-weeks from the start of treatment.

All the defaulters were interviewed or their close contacts by using a semi-structured interview schedule. A questionnaire form was designed which to be has completed by face to face interview. Those who had agreed to participate were interviewed using a pre-tested structured survey questionnaire. Interviews were conducted depending on the language of choice of the participants. An experienced TB clinic supervisor undertook to translate the interview schedule into Tamil before it was conducted.

The questionnaire consisted of two sections

Section one

dealing with patient background characteristics (age, sex, residence and educational level, previous history of treatment with anti-TB chemotherapy and type of TB).

Section two

consist of reasons for irregular treatment.

Inclusion Criteria

TB default patients ,including both pulmonary and extra-pulmonary TB whose ages are in between 10-80 year old registered during the period of January 2014 to June 2014 in RNTCP center as documented in the TB register were included in the study.

Exclusion Criteria

- Patient with incomplete medical records.
- Patient who respond inadequately to questionnaire.
- Patient who becoming restless, too sick, not willing and rushed to the hospital.

Statistical Analysis

Demographic data was summarized in table format using Microsoft word to enhance clarity and facilitate a rapid overview of the results. Data was then entered on spreadsheets using *MS Excel* and later transported to SPSS to describe the data and identify any significant differences between the two groups. Descriptive summary statistics and graphical summaries (bar chart) are presented. Chi-square tests of association were conducted to assess dependence relationships among demographic factors. And fisher's exact test is used to identify the significance in section 2 were used. A 5% level of significance at 95% of confidence interval was used.

Ethical Considerations

Prior to the study, written consent was sought from each study participant after prospective participants had been fully informed on how the study would be carried out and how the collected data would be handled to ensure confidentiality and privacy. Each prospective participant had a right to refuse to participate without negative consequences. Informed consent was obtained from patients and confidentiality and anonymity was assured. Names and addresses of patients were collected only for the purposes of follow-up.

Definition of default

A patient who interrupted treatment consecutively, for more than 2 months at any time during the treatment period.

RESULT

A total of 56 default patients were enrolled for the study during a sixmonth period. Results are in two parts, demographic profile of the patient and factors/ reasons for default TB treatment and improvement after counseling.

Demographic Profile of the Participants

Demographic information was considered important as it provides the socio-cultural descriptive background of the participants regarding the experiences and perceptions of non-compliance to TB treatment. The demographic factors are presented The findings show that the participants (56) were between 10 and 80 years of age. Out of this only 1 (1.78%) patient were below 20 year of age and highest number 23 (41.07%) patient were found in above 50 years of age. Males are more prone to default than female, 45 (81.82%) of the participants were male and 11 (19.64%) were female. The majority of the participants were employed as coolie. 22 (39.28%) of the participants are illiterate. Only 1 (1.78%), patient got educated in university and above. The sociodemographic factors included age, gender, level of education. A total of 56 respondents were interviewed: 44 (78.57%) were category-I default and 12 (21.42%) were category-II defaults and represented in table:1.

Reasons for default TB treatment and improvement after counselling

Out of 56 patients collected, 19 (33.92%) patients felt better and they themselves stopped the medication are accounted for the main reason for non-compliance to treatment. Next 17 (30.35%) patients defaulted

due to lack of proper counseling and unawareness of the frequency and administration of medication, lack of knowledge about common side effects caused by TB medications, and for how long medication should be administered, was found to be another major reason for non-adherence to TB treatment. It can be clearly seen in table 2 and difference between result before and after counselling can be seen in fig:1. In lack of information category, highest number of patients defaulted was due to the reason of feeling better and stopped the treatmentand it accounts 19 (38.92%) defaulters at the prior period of time and after counseling, it reduced to 6 (10.71%) defaulters. 17 (30.94%) were defaulted due to lack of proper counseling and after counseling it wasdrastically compacted to 1 (1.78%), and hence, highest influence was seen in this factor. 5 (8.92%) were defaulted due to fear of side effects and after counseling it reduced to 2 (3.57%). In the lack of motivation category, highest number were defaulted due to postponement till another day and reason for postpone mainly caused due to habit of regular consumption of alcoholics and thus it shows 10 (17.85%) defaulters prior to the counseling and it reduced to 4 (7.14%) defaulters after our counseling. No change could able to make in lack of family support and social stigma factors.

Another main obstacle was adverse reaction due to TB drugs. Total of 11 (19.64%) defaulters, were found to be having fear of adverse reactions and aftergiving counselingon the common reactions that is chance to occur fear towards adverse reactions caused by TB reduced to 7 (12.5%) defaulters. Three obstacles such as moved away from treatment center, no body to accompany to the center and distance from residence and DOTS center were not able to change with our counseling and their number of defaulter number can be seen in table 2 and fig 1.

DISCUSSION

Adherence to tuberculosis treatment regimen is the major and main factor that contributes to its cure rate and better patient health outcomes. For better patient outcome, patient has to firmly follow DOTS regimen and must take drugs in proper way without omitting any doses. In this study of six month period, we have recognized that non-adherence to anti-tuberculosis treatment is still relatively frequent and mostly associated with factors such as felt better and stopped the treatment followed by lack of proper counseling, poor knowledge about anti- tubercular drug by the patients and due to adverse drug reactions.

A Study from South Africa also had reported that treatment interlude was more in men and more default among males than females and it is believed to be due to they are being earning members of the family, and so they could not meet the expense of to get leave on job that frequently ^{5.} Study conducted in Peru also states that males are defaulters because of their job reasons⁷. The present study also shows similar results that, the male sex as the most number in treatment discontinuation i.e., out of 56 default male patientstaken, 45 are male sex .The reason stated behind this says timing not handy(8.92%), moved away from treatmentcenter due to job problems(8.92%), distance from DOTScenter and job site (1.78%).The subjects being economically fruitful members of the family, they are not able to leave the job rather than to leave the treatment. Mostly due to their job related timings and also leave problems for which they cannot be able to find leave frequently.

Study conducted in Bangalore city by Sophia Vijay et al, also points out that, those predicted at risk of default with DOT in a metropolitan setting are most likely to be males, alcoholics, and those missing one or more doses in IP particularly after twelfth dose¹¹. In this current study also, 10/56 (17.85%) number of patients were having habit of postponing in taking medications and keeping for another day and the reason identified behind this is, they are having the habit of taking alcohol and also they are not having proper awareness regarding the consequences of leaving the treatment in between time period of completion of DOTS therapy. Another reason accounts for this includes due to alcohol use they will not get time to go to DOTS center and thus mostly skip the medications due to lack of mental consciousness. During counseling and interacting with the patients we got a clear cut ideathat, why they are using alcohol and their reason was, as they are doing hideous jobs and for getting mental relaxation, they are supposed of using alcoholics. Thus factor of lack of time to take medicines also constitute a factor which is linked with postponement in taking medications.

Study conducted by Chayamithal et al, also states that non-adherence to treatment was found to be more among older patients (22.8%), while very good compliance to treatment was observed betweenpediatric patients (3.5% default)⁸. Similar results were found out in this paper that, default to treatment was found to be more among older patients 41.07% (23/56), while very good compliance to treatment was observed among pediatric patients 1.78% (1/56). The reason behind more default in older patients is mainly due to self-neglect and neglect by family, while the development of more side effects was supposed to be another important reason. Old age is supposed to get adverse reactions easily because of their weak body conditions in most of them. Lack of family support thus can be linked with nobody to

accompany to the DOTS center and this is seen in 5(8.92%) default patients as a factor for their non-compliance. Most of patients who are old aged are defaulted because their family members are having jobs and they are not able to take proper care of patients and other reason is that because of old age conditions and poor health situations most of them are not able to travel alone and nobody is available for them to take them to hospitals accounted for the reason for more defaulter ratio in this present study. Proper care and attention given for these patients and giving counseling to their family members will create some improvement in this field of interest. But in our study no improvement in adherence by counseling for these patients family members can be seen because not just a simple counseling can change the mentality of family members. But a continuous counseling will necessarily make an impact. Thus also lack of family support counts for 8/56 patients (8.92%).

Study conducted by Nabil Tachfouti et al,says that poor literacy level and lack of knowledge is one of the other factor for poor patient compliance. Majority of the respondents were illiterate and most of them only attained primary education. They also suggest that only by education changes can be made^{9.} Similar findings is seen in our research that most of the patient i.e., 22/56 (39.9%) was illiterate and not having education even up to primary level and finds out that as factor for poor knowledge and reason for non adherence in tubercular regimen. As a country like India it will be a great barrier because compared to European countries and concerning aboutthe people in developing country like India, most of the peoples are illiterate and living for their one time stomach filling wages and activities and thus causing for the problem, which can be seen commonly in economically backward classes. But controversy can be also seen that, in most part of the world Indians are showing their professional and educational excellency which cannot be made forbidden or un-noticed but which it is majority overruled by high economic classes. But thinking about peoples currently residing in India,education especially in poor and low income classes lack of at least primary education always remains as one step back compared to developed countries and thus it needs to be improved.

The main reason for not completing the treatment was the impression of being cured. Several studies have reported feeling cured as the main reason for defaulting. In Zambia, the major factor leading to non-adherence included patients beginning to feel better and stopping the medications (45.1%) and in Indonesia, feeling better was the most frequently mentioned reason (47%). Considering that patients start feeling well after only a few weeks of treatment, it is of the paramount importance to explain to patients the importance of completing their treatment although they don't feel the need for it and might experience side-effects. To minimize defaulting, patients should be given ample counseling at start of treatment of the disease, with enough explanation on the disease, its treatment and also possible side-effects and the availability of means to manage them.^{9, 15, 37} This current paper also identifies that feeling better and stopping treatment 38.92% (19/56) as the most common reason of default. Most of the patients will get subside of their symptoms within one or two month of commencement of the treatment and most of them think that problems have cured. This is happening because of lack in proper information regarding medications. Only way to get reducing this factor is by complete and proper patient counseling. Other important reasons were lack of counseling 30.94% (17/56), fear of adverse reactions 19.64% (11/56), fear of side effects 8.92% (5/56).

Most of the reasons of non-Compliance can be averted by proper counseling of intention group. Hence to achieve the goal of RNTCP, proper counseling of intention group must be given top precedence 13, 7, 9. Based upon various results obtained during this research work we also suggest that proper counseling needs to be done efficiently. Counseling can make patient better informed about the drug and also we can make patient better adhere to the treatment regimen. Main target in our research work is done on counseling given for the patient and thus making difference in adherence criteria. Better and small improvement in the adherence towards medication in DOTS regimen can be seen during our counseling and it can be seen clearly in the graph of before and after counseling (fig.1). Counselling was done to patient and patient care takers .Various TB related pamplets about spread, its common symptoms ,side effects less likely to come inculding leaflets was all given to the patient. Before counseling, the factor of lack of counseling and default ratio it was found 17 default patients and it is clearly seen that due to counseling it was improved about 70% and patients got informed about TB medications and all its possible side effects, it period of course and its importance in the completion of course. Thus this paper clearly concentrates on importance of counseling among TB patients, that by proper and relevant counseling given to the patients regarding all the effects and benefits of the treatment medical field can make a better change in TB patients concept towards tuberculosis and its treatment.

Also without mentioning about this factors it seems to be negative, that due to counseling no improvements were made before and after in these following factors such as distance from DOTS center, timing not convenient, lack of family support, moved away treatment center. All these factors are associated with job related factors and it seems to be the main reason for the problem for no changes.

Because job is the primary source of income for most of the members and they are only earning members of the family and they are not able to get leave in job more frequently. But a continuous counseling can make some impact even if it is not very high impact.

CONCLUSION

Keeping in mind all the chief reasons of default, preliminary counseling by the health personnel explaining the treatment plan before starting of the treatment, periodic inspiration of patients, and prompt action to tackle any problem will enhance compliance. This can be overcome by providing effective counseling and providing patient information leaflets and setting alarms in their mobile phones to take drug properly.

Remembering to take tablets every day can be difficult and an assessment at the beginning of treatment and during follow-up appointments should consider whether a patient is able to take their drugs without supervision. Simple measures can help, such as providing the patient counseling with information about the side-effects before starting treatment and reinforcing this information during following consultations. Most of the disincentives to take TB treatments are associated with troublesome side-effects of medication, although a small percentage of patients will develop serious adverse reactions, such as hepatotoxicity. As a lot of patients seem to have difficulty with their treatment in the first few weeks, it is advisable to monitor them frequently at this stage. A contact number to call for medication advice encourages people to telephone with problems rather than stop their treatment.

To ensure proper monitoring more personnel must be recruited and trained to do house to house monitoring of patients already on the DOTS program. The community health workers, volunteers as well as non-governmental health providers could be recruited to monitor the DOTS program. This will prevent patients from giving excuses of not having money to go to the hospitals to take their drugs. The house to house monitoring would be made effective if a detailed history/data on each patient is recorded and made available to the monitoring personnel.

Some work should also be done on anti-tuberculosis drugs to decrease the number of pills patient have to consume. Further availability of some medicines required for treating side effects can be ensured as side effects following treatment is a major problem among patients.

In this study of six month period, we have identified that non-compliance with Anti-Tuberculosis treatment is still relatively frequent and mostly associated with factors such as felt better and stopped the treatment, lack of counseling and due to adverse drug reaction. With this study we are suggesting that proper counseling and evaluating the factor for non-compliance and making necessary action can play an important role in improvement of treatment adherence and improve quality of life in TB patients.

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Table 1: Demographic profile of the patient

Background Characteristic		Number	Percentage	Significance	
				X ² , d.f	P value
	< 20	1	1.78%		
	20-29	11	19.64%		
Age (years)	30-39	9	16.07%	18.364	0.0010*
	40-49	12	21.43%		
	50+	23	41.07%		
Sex	Male	45	81.82%	14.351	0.0002*
	Female	11	19.64%		
	Illiterate	22	39.28%		
Education	Primary	17	30.35%	15.863	0.0012*
	Secondary	16	28.57%		
	University & above	1	1.78%		
	<u> </u>	-			
Cigarette Smoking	Smoker	32	57.14%	0.76361	0.3822
	Non-smoker	24	42.85%	0.7 0301	
Alcoholism	Alcoholic	34	60.71%	1.7231	0.1893
	Non-alcoholic	22	39.28%	1.7251	
Type of TB	Pulmonary	54	96.24%	35.601	<0.0001*
	Extra pulmonary	2	3.57%	33.001	
Default Category	CAT 1	44	78.57%	12.651	0.0004*
	CAT 11	12	21.42%	12.051	

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Factors	Reasons	Before Counseling	After Counseling	Significance (Fisher's Exact Test)	
ractors	Reasons	Number (%)	Number (%)	P value	
	Fear of side effects	5 (8.92)	2 (3.57)	0.1667	
	Felt better and stopped treatment	19 (38.92)	6 (10.71)	<0.0001*	
Lack of	Lack of counseling	17 (30.94)	1 (1.78)	<0.0001*	
Information		n=41	n=9		
	Difficult to take so many pills	3 (5.35)	2 (3.57)	1.0000	
	Postponement till another day (Eg: alcoholics)	10 (17.85)	7 (7.14)	0.0108*	
Lack of	Others (no faith in treatment, rumorsetc)	6 (10.71)	3 (5.35)	0.1818	
Motivation	Lack of family support	5 (8.92)	5 (8.92)	1.0000	
	Social stigma	1 (1.78)	1 (1.78)	1.0000	
		n=25	n=18		
	Moved away from treatment center	5 (8.92)	5 (8.92)	0.1818	
	Timing not convenient	5 (8.92)	3 (5.35)	0.4444	
	Nobody to accompany to the center	4 (7.14)	4 (7.14)	1.0000	
	Distance from residence and DOTS center	1 (1.78)	1 (1.78)	1.0000	
Obstacles	Attitude of DOTS provider	3 (5.35)	2 (3.57)	1.0000	
	Adverse reaction	11 (19.64)	7(12.5)	0.0373*	
		n-20	n-22		

Table 2: Reason for default TB treatment and improvement after counseling

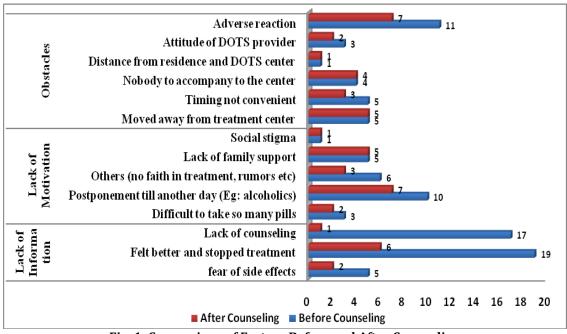


Fig. 1: Comparison of Factors Before and After Counseling

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