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FACTORS CONTRIBUTING TO NON-COMPLIANCE ON DOTS REGIMEN IN SELECTED URBAN DOTS CENTER IN BANGALORE.

S. Jenifer Helen Sathya [1*], J. Violet Jayamani[2], Bai Jayanti Mishra [3]

[1]Tutor, St. John's National Academy of Health Sciences, Bangalore, Karnataka, India
[2]Associate Professor, St. John's National Academy of Health Sciences, Bangalore, Karnataka, India
[3]Additional Professor, St. John's National Academy of Health Sciences, Bangalore, Karnataka, India

Corresponding Author

S. Jenifer Helen Sathya
Email:- jeniferhelensathya@gmail.com

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ABSTRACT

Introduction: Tuberculosis (TB) is a public health problem the world over, with a great part of its morbidity and mortality concentrated in developing countries. The therapeutic regimens as recommended by World Health Organization (WHO) have been shown to be highly effective for both preventing and treating tuberculosis but noncompliance to DOTS regimen is still a problem and is the most important cause of failure of initial therapy and relapse. Noncompliance to DOTS regimen has been cited as a major barrier to the control of TB. There are different factors responsible for the noncompliance of TB. Hence the present study intends to identify various factors contributing to noncompliance to treatment in patients on DOTS under RNTCP.Methods: Descriptive cross sectional research design was used in this study. The DOTS centers were selected by convenient sampling and 96 Cat II sputum positive defaulter patients were selected by purposive sampling technique. A semi structured interview schedule was used to obtain demographic data and factors contributing to noncompliance to DOTS regimen. The collected data was analyzed using descriptive and inferential statistics. Results: In the present study 62(64%) of the subjects with category II sputum positive defaulter were in age group of more than 35 years. Gender wise 82(85.4%) were males. The most common factor contributing to non-compliance 82(85.4%) were found to have habit of tobacco chewing in past, 10(10.4%) believed that alternative medicine cures TB, 13(13.5%) had fear of discrimination, 88(91.7%) had an improvement during initial treatment, 86(89.6) found hard to take too many pills at a time, 60(62.5%) experienced side effects like GI upset and 59(61.5%) fatigue. Regarding health care services 7(7.3%) waited for a prolonged period in the clinic and 6(6.3%) travelled long distance to clinic and 4(4.2%) felt hard to reach the clinic. Moreover, there were significant associations between selected demographic variables and alcohol consumption, health care services, area of residence and smoking of the defaulters.Conclusion: This study provided the reasons for defaulting from DOTS regimen and hence the need for guidance and counseling that will help to decrease the default rate and increase the cure rate.

Key Words: Tuberculosis, noncompliance, factors contributing, DOTS, Cat II sputum positive.

INTRODUCTION

Tuberculosis (TB) is a public health problem the world over, with a great part of its morbidity and mortality concentrated in developing countries [1]. It is an infectious disease caused by Mycobacterium tuberculosis, which is transmitted through the air or by ingesting infected milk or meat (Bovine TB) and it is both preventable and curable. People who have pulmonary tuberculosis can infect others through droplet infection when they cough, sneeze or talk [2]. The prevalence, pattern of presentation and the mortality vary from one country to another and from one region of a country to another. These variations depend on prevailing social factors such as socio-economic status of the people, living conditions, level of development of health infrastructure, quality of available drugs and the

degree of drug resistance to Directly Observed Treatment Short course (DOTS) [3].

Globally 9 million new cases of all forms of TB occur annually and 3 million people die each year. Of these, 95% of TB cases and 98% of TB deaths are contributed by developing countries. India accounts for nearly 1/3rd of global TB cases. In India everyday about 20,000 people become infected, more than 5000 develop the disease and more than 1000 die due to the disease [4]. Though National Tuberculosis programme (NTP) was in existence since 1962 there is no appreciable change in the epidemiological situation of TB in the country. In view of this situation in 1992, Government of India along with World Health Organization (WHO) reviewed TB situation and performance of NTP and decided to give a new thrust to TB control activities. The Revised National Tuberculosis Control Programme (RNTCP) was formulated and thus recommended DOTS strategy the most systematic and cost effective approach to revitalize the TB control programme in India [5].

RNTCP saving more than 2.8 million lives is the biggest achievement, RNTCP has special emphasis to areas classified as tribal and backward, RNTCP is well on track to achieve Millennium Development Goal (MDG) of halting and beginning to reverse the spread of the disease. In the year 2013 RNTCP put 1416014 patients on DOTS treatment [6]. The DOTS is accessible to more than a billion people in India. In DOTS an observer health worker or trained community volunteer other than family member) watches and supports the patient in taking their drugs. Direct observation ensures treatment adherence, with the right drugs in right doses and at right intervals [7]. In the four or five month continuation phase when the bacterial load is far lower, at least the first of each of the thrice weekly doses is directly observed. Medications for both phases of treatment are kept in an individual box containing the entire course of treatment for a single patient. Diagnosis and treatment are free of charge to the patient [8]. The RNTCP performance has high cure and low default rates after its implementation. The unique feature of RNTCP is the use of blister combi packs in Patient Wise Drug Boxes (PWDB) for adults and Weight Band wise Drug Boxes (WBDB) for paediatric cases which contain drugs for the entire course of treatment.

Compliance to DOTS plays an important role in the outcome of the treatment. Compliance is defined by WHO as The extent to which a person's behaviour taking medication, following a diet and executing lifestyle changes, corresponds with agreed recommendations from a health care provider [8]. Here the responsibility is entirely on the patient to comply to the medical advice with inherent assumption that diagnosis and treatment is correct and good information about the disease is given. The term compliance considers the impact of socio-cultural context and the interactions between providers and patients. It has been shown that long term compliance depends on how well the regimen fits into a person's life style. Most of the patient compliance looks to the clinical perspective. Such a perspective excludes system factors and other external constraints have an improved understanding of compliance that includes some patient perspectives. Patient's were found to weigh up the expected benefits, usually symptom relief against the severity of their symptom and the perceived risk of treatment (side effects, time and effort involved, stigma etc). In chronic illnesses, forgetfulness or boredom has contributed to noncompliance. This clearly indicates need to examine compliance from a patient and system perspective [9].

Non-compliance to DOTS is defined as not coming to the clinic for treatment for more than thirty consecutive days. It is an important barrier for controlling TB because it is related with treatment failure, the development of drug resistances, spreading of infection and increased treatment costs [7]. The adoption of DOTS has given impressive results with higher treatment success being reported from developing and industrialized countries. But the noncompliance to treatment still continues to occur in certain situations and is a matter of concern. Noncompliance from treatment has been one of the major obstacles to treatment and an important challenge for TB control. Inability to complete the prescribed regimen which is quite common in self-administered treatment is an important cause for treatment failure, relapses, acquired drug resistance and ongoing transmission of infection. An efficient network of health infrastructure with committed treatment organization is most essential for the success of DOTS. The identification of factors that influence the noncompliance to DOTS regimen, timing, pattern of defaulting and characteristics of patients who default will be helpful in planning intervention for reducing default in retreatment of tuberculosis.

Objectives of the Study

1) To assess the factors contributing to noncompliance of DOTS regimen by TB patient.

2) To determine the association between factors contributing to noncompliance with selected demographic variables.

METHODOLOGY

A descriptive cross sectional research design was adopted as it describes situations which is existing in the world and provides information regarding the factors contributing to non-compliance on DOTS regimen among Tuberculosis patients. This study was conducted in 9 Tuberculosis Unit (TU) in Bangalore. The TU's are in east 3 (Adugodi TU and coxtown TU, Halsurer TU), in west 2 (Geleyarbalaga TU and JJR nagar TU) and in south 4 (Banashankari, Dasappa, Hanumanthanagara, Jaya nagar). By using Purposive sampling method the sample of 96 category II sputum positive defaulters who attend the

urban DOTS centres under RNTCP in selected areas of Bangalore and meeting the inclusion criteria were selected. The instruments used were, semi-structured interview schedule.

Data was collected after obtaining written permission from district tuberculosis officer of Bengaluru and also approval from IEC. The investigator met the Medical Officer of each Tuberculosis control unit (MO-TC) of Bangalore and sought their co-operation. And also met the senior treatment supervisor (STS) and health visitors of the respective TU, explained them about the study and sought their co-operation in tracking all the patients on DOTS. The cat II sputum positive defaulter patients were selected by using purposive sampling based on the inclusion and exclusion criteria; a total of 96 samples was selected for the study using the register in the DOTS centre. Written informed consent was obtained from the cat II sputum positive defaulter patients and by using semi structured interview schedule, the investigator interviewed them in each patient's home. The data was collected from9/11 /15 to 18/12/15. The maximum duration for data collection for one subject was approximately 30 min.

RESULTS

Among the subjects, 29(30.2%) had the habit of smoking tobacco, 14(14.6%) had the habit of chewing tobacco and 42(43.8%) consumed alcohol.Regarding family members,93(96.9%) of the patient's family were aware about patients TB status and for 83(86.50%) patients family members accompanied them to the hospital.

Among the study subjects, 93(96.9%) believed that their health information should be kept confidential and 90(93.8%) were motivated by DOTS volunteer and believed that TB was curable, 10(10.4%) believed in alternative medicine and 13(13.5%) had fear that people will discriminate them because of their TB status as explained in Table 2.

Table 3, depicts that 88(91.7%) of the people improved in their health condition after initiation of treatment, 56(58.30%) had side effects of the therapy, 86(89.6%) of patients complained that it was hard to take so many pills at a time and 85(88.5%) of patients said that duration of treatment is too long.

The Table 4, shows that 60(62.5%) had the side effects of GI upset, 59(61.5%) had the symptoms of fatigue. Also, 93(96.9%) of them felt that treatment should be started as soon as the person was diagnosed and 15(15.6%) were not aware that TB can affect other parts of the body other than lungs. The other findings were that 95(99%) of the patients found the doctors and staff of DOTS centre friendly and the DOTS medicine was always available at the centre, 94(97.9%) were satisfied with the care provided in the DOTS centre and 93(96.9%) of patient's had counselling session before they were started the treatment.

Table 5, depicts significant association between demographic factors and DOTS. Smokers above the age of 35 years, male smokers, males who consume alcohol and those staying in urban slums were found to be at higher risk non-adherence to DOTS.

Table 1. Distribution of CAT II sputum positive defaulter patients according to their demographic data. n =96

S.NO	Demographic Factors		Frequency (F)	Percentage (%)
1	Age	<35	34	35.40
		>35	62	64.00
2	Sex	Male	82	85.40
		Female	14	14.60
3	Religion	Hindu	72	75.00
		Others	24	25.00
4	Marital Status	Married	76	79.20
		Unmarried/widow/separated	20	20.80
5	Education	Illiterate	34	35.40
		Literate	62	64.60
6	Occupation	Unemployed	72	75.00
		Employed	24	25.00
7	Socio-economic Status	Above Poverty Line Card	09	9.40
		Below Poverty Line Card	87	90.60
8	Area of residence	Urban	35	36.50
		Urban slum	61	63.50
9	Type of family	Nuclear	89	92.70
		Joint	07	7.30
10	Duration of residence	<2yrs	14	14.60
		>2yrs	82	85.40
11	Presence of concomitant disease	Yes	12	12.50
		No	84	87.50

Table 2. Patient attitude towards TB n=96

S.NO	Characteristics	YES	
		Frequency (F)	Percentage (%)
	Tuberculosis is a curable disease	90	93.80
	Tuberculosis can be cured if treatment is completed	87	90.60
	People discriminate due to Tuberculosis status	13	13.50
	Alternative medicine cures tuberculosis	10	10.40
	DOTS volunteer motivates	90	93.80
	DOTS medicine can be skipped when fasting	21	21.90

Table 3. Medicine related non-compliance factors n =96

S.NO	Characteristics	YES	
		Frequency (F)	Percentage (%)
1	Improvement in general condition after initiation of treatment	88	91.70
2	Presence of side effects at the initiation of treatment	56	58.30
3	Felt better and stopped DOTS	19	19.80
4	DOTS can be stopped as side effects appear	29	30.20
5	Continuous DOTS intake creates problem	83	86.50
6	Duration of DOTS treatment is too long	85	88.50
7	Too hard to take too many tablets at a time	86	89.60

Table 4. Side effects of anti-tubercular medicines n=96

S.NO	Side effects	YES	
		Frequency (F)	Percentage (%)
1	Skin rashes	11	11.50
2	Drowsiness	56	58.30
3	Fatigue	59	61.50
4	Gastrointestinal upset	60	62.50
5	Joint pain	35	36.50
6	Nausea	52	54.20
7	Loss of hearing	03	3.10
8	Burning in hands and feet	13	13.50
9	Jaundice	04	4.20

Table 5. Associations between factors contributing to non-compliance n =96

Factors	Yes (F)	Yes (%)	No (F)	No (%)	Test of significance 'p' value
	Nonadherence to DOTS				
Tobacco Consumption					
<35 yrs	05	17.2	29	43.3	0.014*
>35 yrs	24	82.8	38	56.7	
Tobacco Consumption					
Male	29	100	53	79.1	0.019*
Female	00	00	14	20.9	
Alcohol Consumption					
Male	41	97.6	41	75.9	0.003#
Female	1	2.4	13	24.1	
Area of residence					
Urban	00	00	35	41.7	0.013#
Urban slum	12	100	49	58.3	

* Chi-square, # Fisher's exact test

DISCUSSION

TB patient's non-compliance to treatment regimens could be due to varied reasons. The present study assessed the factors contributing to non-compliance among category II sputum positive defaulters with regard to substance abuse, family support and attitude towards TB, knowledge regarding TB and DOTS medicines, side effects and location of TU centres.

In this study majority (64%) of the defaulter were males more than 35 years of age. Study [10, 11] done to assess the defaults among tuberculosis patient also found the most defaulters were above 35 years of age.

In this study majority of them were males 82(85.4%), so male were more noncompliant to treatment than their counterparts. Previous studies have also shown that males are more prone to default. This is probably because, men travel more either because of their work or social reasons and may forget to take the medicines. In most instances, men are the bread winners for the family and may not be able to visit the DOTS Centre or DOTS provider during the initial intensive phase of treatment due to financial or occupational reasons. Educated (bachelors and master degree) people were noncompliant when compared to less educated (1^{st} – 12^{th} standard) and this correlates with other similar studies [9, 10]. This was because the educated had a consistent job with fixed working hours and found it difficult to make time to visit the DOTS Centre or DOTS provider.

Most of the subjects (75%) were unemployed and their socio economic status revealed 90.6% to be below poverty line. Majority of the patients belonged to low socioeconomic status and faced economic problem during their treatment either due to loss of daily wages or due to travel expenses. Most attributed their loss of job because either they were irregular to work when they were on category I treatment or they were so sick that they were not able to continue their work.

Majority of the patients were (63%) staying in underprivileged areas 'slum' and 85.4% of them were staying at the same residence for more than two years. People residing in unsanitary condition along with poor standard of living which are common combination in slums were at higher risk of nonadherence to DOTS when compared to urban residents and it was found to significant.

In the present study 99% were aware that use of tobacco and consumption of alcohol interferes with recovery from TB, 85.4% had the habit of chewing tobacco, 69.8% had habit of smoking tobacco and 56.3% of them used alcohol. Similar observations have been made in another study [8]. Alcoholism and smoking has been identified as an important predictor of non-compliance. Elicitation of history of substance abuse, prior to treatment initiation may help in identifying potential defaulters needing special attention and counseling during treatment. Among the tobacco and alcohol users, people above 35 years of age and males did not comply with DOTS regimen. The assumption among the patients was that use of tobacco and consumption of alcohol helps reduce their tension and helped them cope with their diagnosis of TB.

When considering the attitude of patients towards TB, majority of them (96.9%) believed that their TB status would be kept confidential by health worker, 93.8% knew that TB was a curable disease and 93.8% were motivated by DOTS volunteer. About 13.5% of patients felt that they were discriminated due to tuberculosis status and 10% of them believe in alternative medicine cures tuberculosis which was supported by another study [7]. Hence health personnel should be sensitive to this issue and evolve suitable motivation strategies. Majority of the subjects (82.3%) said that going to clinic resulted in loss of income. As they were males and were the earning members of the family. They could not afford to leave from their work place and had fear of losing their jobs if they took leave repeatedly.

The drug also had an influence for non-compliance. About 91.7% felt that they improved in their general health condition once they started their treatment, 89.6% said that they were scared of taking so many tablets and it was difficult to swallow them at once, 62.5% had GI upset and 61.5% had fatigue due to the side effects of the drugs. The findings had a similar correlation with another study [12]. They were nausea, vomiting, giddiness, headache, skin rashes, tightness in chest and cough. The reasons for higher incidence of side effects could be due to continued practice of taking medication on empty stomach. The DOTS providers' needs adequate orientation regarding possible side effects and prompt referral of patients to the medical officer or higher centres. Frequently reported minor side effects could be successfully dealt with proper instructions on drug consumption, reassurance to patients and prompt symptomatic treatment before it leads to default.

The subjects (85%) also reported that too long to complete as supplemented by another study [7]. It is encouraging to note that 93% of the subjects said that once diagnosed it is important to start the treatment immediately, 86% of the subjects said that TB can affect anyone irrespective of income and 81% of them said that TB is diagnosed by sputum sample and it can result in death if not treated. This shows that the health education about the disease, diagnosis and treatment prior to starting treatment will be effectively improve the knowledge about TB.

In the present study majority of them were satisfied with the health care services i.e. 99% felt that attitude of doctors and staffs of the DOTS centre were friendly, DOTS medicine is always available and hence the supply chain system for medicines was satisfactory and 97.9% of them were satisfied with the care provided in the DOTS centre as found in similar study [13]. Health worker attitudes, timings of the TU, availability of medicines and accessibility issues (distance and cost of

travel to the health facility) were other important factors affecting TB treatment compliance.

Implication of the study

Nursing education

This study reveals the factors contributing to non-compliance among category II sputum positive defaulter. This could provide the basis for approaches and techniques to be used by faculty and students for health education programmes. The prospective nurses should be made aware of their role in the society towards the prevention of defaulters. The nursing education curriculum may consist of different strategies of imparting information so the student nurses should be made to utilize the best suitable way to impart knowledge to TB patients in order to overcome the factors hindering patient's compliance.

Nursing Practice

The nurses play a major role in Health care delivery system as they work in the immediate environment of the patients. Hence they have more opportunities to conduct counseling, awareness and motivational programmes based on the identified needs and problems. Assessing the needs and identifying the problems facilitate the care planning and application of nursing process efficiently.

Nursing Administration

Nurse as an administrator should take great interest in formulating policies for short term and long term teaching strategies to improve knowledge and compliance among TB patients. These findings will help the nurse administrators to take initiatives in organizing, individual and group health education session for TB patients and improving the interpersonal communication skills of the health providers. Student nurses are also being motivated to involve in a various health promotion activities for TB patients.

Nursing Research

- Further research needs to be conducted to find the methods to motivate the people to adopt preventive measures with regard to TB as in the present scenario.
- More research is needed to identify the comparison between male and

Female non-compliance to TB treatment in Bengaluru.

- Future research can be done on non-compliance by respondents on ART treatment

Should be conducted.

Limitations

- The study is restricted to urban DOTS centre in Bengaluru.
- The data is only based on the response of the subjects not by observation.

Recommendations

- The study can be done by case control research design.

The study can be conducted in different settings.

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Nil

CONFLICT OF INTEREST

No interest

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