AN EPIDEMIOLOGICAL STUDY OF DETERMINANTS OF DEFAULTER UNDER REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAM IN OLD CITY OF HYDERABAD

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ABSTRACT

Introduction: In India TB report 2014 it was stated that, out of the estimated global annual incidence of 8.6 million TB cases, 2.3 million were estimated to have occurred in India till 2012. As per WHO, Tuberculosis prevalence per lakh population has reduced from 465 in year 1990 to 230 in 2012. Defaulting from treatment has been one of the major obstacles to treatment management and an important challenge for TB control. To ensure treatment adherence, Directly Observed Treatment - Short Course (DOTS) is a main strategy. It becomes imperative to understand the determinants of default under DOTS so that necessary actions can be taken up to prevent defaults under the program. Hence, the present study was undertaken to study the determinants of default under DOTS.

Material and methods: Case control study was carried out in "Bhavani Nagar" urban slum area of Hyderabad in old city and study subject were selected. Study duration was from 1st January 2011 to 31 December 2012 and data was collected from June 2013 to July 2013 by interviewing study subjects. The data collected was entered and analyzed using epi_info 6.04d. The study has been conducted after being approval from Institutional Ethical Committee.

Results and conclusion: The odds of getting default were 2.4 times more when the study subjects belongs to OBC caste but was not found statistically significant. The risk of getting defaulter was 3.2 times more in study subjects studied less than higher secondary when compared with study subjects studied more than equal to higher secondary but was not found statistically significant. Major reason for defaulting was disappreance of the symptoms i.e. 33.3%, followed by intolerance of drugs(26.1%). It was found that having nuclear family is one of the determinant for defaulting. It was also seen that old cases of TB were associated with defaulting this may be due to the drugs intolerance or due to the disappearance of symptoms or their adherence to treatment requires more counseling. Defaulting was also found significantly associated with DOTS provider who were from the health department.

Key Words: Case control study, Tuberculosis, Defaulters

INTRODUCTION

India is the second-most populous country in the world one fourth of the global incident Tuberculosis (TB) cases occur in India annually. In India TB report 2014 it was stated that, out of the estimated global annual incidence of 8.6 million TB cases, 2.3 million were estimated to have occurred in India till 2012. India's TB control programme is on track as far as reduction in disease burden is concerned. There is 42% reduction in TB mortality rate by 2012 as compared to 1990 level. Similarly there is 51% reduction in TB prevalence rate by 2012 as compared to 1990 level. These estimations were based on Revised National Tuberculosis Control Program (RNTCP) data, prevalence surveys in India conducted between 2007-2010, National Annual risk of tuberculosis infection(ARTI) surveys and mortality surveys conducted in 2005. Tuberculosis prevalence per lakh population has reduced from 465 in year 1990 to 230 in 2012. In absolute numbers, prevalence has reduced from 40 lakhs to

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28 lakhs annually. Tuberculosis incidence per lakh population has reduced from 216 in year 1990 to 176 in 2012. [1]

Defaulting from treatment has been one of the major obstacles to treatment management and an important challenge for TB control.[2,3] Inability to complete the prescribed regimen which is quite common in self-administered treatment[4], is an important cause for treatment failure, relapse, acquired drug resistance and on-going transmission of infection[5]. The consequences of default could be disastrous particularly in the context of intermittent Short Course Chemotherapy (SCC) regimens. Directly Observed Treatment - Short Course (DOTS) is a main strategy under RNTCP to ensure treatment adherence, wherein each dose of treatment is given under the observation of a health worker. The adoption of DOTS has given impressive results with higher treatment success being reported from developing[6]and industrialized countries[7]. Yet, default continues to occur in certain situations and is a matter of concern. The challenges encountered while implementing DOTS vary from place to place depending on the geographic terrain, demographic structure and socio-cultural milieu. The major thrust of RNTCP is achieving a cure rate of more than 85%[6]. Strict adherence to Directly Observed Treatment is likely to minimize defaults and is therefore essential for the desired treatment success as shown in study at Bangalore[7]. It becomes imperative to understand the determinants of default under DOTS so that necessary actions can be taken up to prevent defaults under the program. Hence, the present study was undertaken to study the determinants of default under DOTS.

AIMS AND OBJECTIVES

The present study was undertaken to study the determinants of default under DOTS programme

MATERIAL AND METHODS

Present Case control study was carried out in "Bhavani Nagar" urban slum area of Hyderabad in old city. A "case" was a defaulter TB patient who received anti-TB treatment for one month or more from any source and had not taken anti-TB drugs consecutively for two months or more. All cases which defaulted during 1st January 2011 to 31 December 2012 at Bhavani Nagar area using RNTCP definition were included in the study. The "control" was a case of tuberculosis that has completed treatment during 1 January 2011 to 31 December 2012 and was not a defaulter at any point of time. The Quantitative data was collected for the study purpose from June 2013 to July 2013. The quantitative data was collected by interviewing the defaulters and the persons who have completed the treatment in predesigned and pre-tested questionnaire after taking informed consent. The socio-economic status(SES) was based on the different ration card provided by state government which mentions the Below poverty line(BPL) and Above poverty line(APL) family. The data collected was entered and analyzed using epi_info 6.04d. The study has been conducted after being approval from Institutional Ethical Committee. The defaulters in the study area were interviewed after informed about the importance of the treatment. If any problem detected, defaulter was counseled for referral.

RESULTS

Table 1: Determinants of Defaulters.

Variables		Cases N =15(%)	Controls N = 15(%)	p-value	Odds ratio
Socio-demographic determinants					
Age	< 40 years	13(86.6)	13(86.6)	1	1
	>40 years	2(13.4)	2(13.4)		
Sex	Male	8(53.3)	7(46.7)	1	1.3
	Female	7(46.7)	8(53.3)		
Caste	General	7(46.7)	4(26.7)	0.4	2.4
	OBC	8(53.3)	11(73.3)		
Occupation	Household work	8(53.3)	9(60.0)	1	0.76
	Labourer class	7(46.7)	6(40.0)		
SES	APL	3(20.0)	3(20.0)	1	1
	BPL	12(80.0)	12(80.0)		
Family	Joint	4(26.7)	11(73.3)	0.02	0.13
	Nuclear	11(73.3)	4(26.7)		

Table 1: (Continued)

Variables		Cases N = 15(%)	Controls N = 15(%)	p-value	Odds ratio
Educational status	< Higher Secondary	5(33.3)	2(13.3)	0.3	3.2
	> Higher Secondary	10(66.7)	13(86.7)		
Marital status	Unmarried	6(40.0)	3(20.0)	0.4	2.6
	Married	9(60.0)	12(80.0)		
Personal Determinants					
Tobacco use	Yes	3(20.0)	0(0.0)		UD
	No	12(80.0)	15(100.0)		
Alcohol consumption	Yes	1(6.7)	3(20.0)	1	0.4
	No	14(93.3)	12(80.0)		
Reffered	Self	3(20.0)	4(26.7)	1	0.68
	Health worker & others	12(80.0)	11(73.3)		
Migrated	Yes	4(26.7)	0(0.0)		UD
	No	11(73.3)	15(100.0)		
Diagnostics Determinants					
Place of diagnosis	Govt hospital	14(93.3)	15(100.0)		UD
	Private hospital	1(6.7)	0(0.0)		
Type of cases	Old	6(40.0)	2(13.3)	0.02	4.3
	New	9(60.0)	13(86.7)		
Type of patient	Pulmonary	7(46.7)	12(80.0)	0.12	0.21
	Extra pulmonary	8(53.3)	3(20.0)		
Category of patient	Cat I	9(60.0)	13(86.7)	0.21	0.23
	Cat II	6(40.0)	2(13.3)		
Treatment Determinants					
DOTS provider	Health system	10(66.7)	1(6.7)	<0.05	28
	Volunteer/Other	5(33.3)	14(93.3)		
Reffered for side effects	Self	6(40.0)	6(40.0)	1	1
	Health worker	9(60.0)	9(60.0)		
Counseling for continuation of the treatment	Doctor	7(46.7)	10(66.7)	0.46	0.43
	Health Worker	8(53.3)	5(33.3)		

Table 1 above shows that, maximum numbers of study subjects were from below age of 40 years(86.6%), similar were in cases and controls. Age was not found to be significantly associated with defaulters. Male and female study subjects were approximately equally affected in both cases and controls. Study subjects belonging to OBC caste were more in cases(53.3%) and the general caste were more in controls(73.3%). The odds of getting default were 2.4 times more when the study subjects belongs to OBC caste but was not found statistically significant. Study subjects doing household works and those doing labour work were 53.3% and 46.7% in the cases respectively where as in controls 60% were doing house-hold work and 40 % were in labour. It can be observed from the above table maximum number of study subjects were belonging to Below Poverty Line(BPL) i.e 80% and 20% were in Above Poverty Line(APL) and study subjects were similar in cases and controls both.

In above table 1 it can be observed that 26.7% and 73.3% study subjects were from joint and nuclear family respectively in cases and in controls it was vice versa. It was observed that the odds of becoming defaulters was 0.13 times less when the study subject belong to nuclear family compared to joint family and was found statistically significant(p <0.05). When observed in above table

about educational status, 66.7% and 86.7% study subjects were studied more than equal to higher secondary in cases and control where as 33.3% and 13.3% were studied less than higher secondary level of schooling in both cases and controls. The odds of getting defaulter was 3.2 times more in study subjects studied less than higher secondary when compared with study subjects studied more than equal to higher secondary but was not found statistically significant. From above table 1 it can be seen that study subjects married and unmarried were 60% and 40% respectively in the cases and in control they were 80% and 20%. Odds of getting defaulter was 2.6 in married when compared to unmarried but was not found statistically significant(p >0.05)

In the above table 1, it can be observed that 20% study subjects were tobacco consumers in cases and there were no tobacco consumer in the control group. It can be observed from above table that 6.7% study subjects were consuming alcohol and 20% were of the study subjects in control groups were consuming alcohol group and was not having any significance in determining the defaulters. Most of the study subjects in cases were referred by health workers & other (80%) while the in controls they were 73% and there was no significance. Above table shows that among the cases group 26% study subjects migrated while no study subjects migrated in the control group.

In above table 1, it can be seen that only 6.7% study subjects in the cases were diagnosed in private hospital while all of the study subjects were diagnosed in government hospital. Above table shows that old TB study subjects were 40% and 13.3% in the cases and control group respectively. Odds of getting defaulter of 4.3 times more in old study subjects compared to newly diagnosed TB and the association was found statistically significant(P < 0.05).

Above table 1, shows that in cases group pulmonary and extra pulmonary TB diagnosed study subjects were 46.7% and 53.3% respectively while they were 80% and 20% in respectively in control group. Above table shows that in category of TB, study subjects were 60% in cat I and 40% in cat II in cases group and 86.7% and 13.3% in cat I and cat II respectively in control group.

Above table 1, shows that DOTS providers in the cases group were personals in the health system(66.7%) and volunteers were 33.3%. While in control group DOTS providers were personals in the health system(6.7%) and volunteers were 93.3%. The odds of getting defaulter was 28 times more if the DOTs provider was the personal from the health system compared to volunteer and was found statistically significant(p <0.05). Above table shows that study subjects those witnessed side effects after treatment were referred equally by

self(40%) and health worker(60) equally in cases group and control group. From above table it can be observed that doctors counseled 46.7% study subjects for continuation of the treatment and health worker to 53.3% study subjects in cases group. In control group it was observed that doctors counseled 66.7% study subjects and health worker 33.3% study subjects for continuation of the treatment.

Table 2: Reasons for defaulting

Reasons for defaulting	Cases, N =15(%)
Disappearance of symptoms	5(33.3)
Taken private treatment	3(20.0)
Needed help of attendant	1(6.7)
Missing of work	2(13.3)
Intolerance to drugs	4(26.7)

Above table 2 shows that major reason for defaulting was disappreance of the symtoms(33.3%), followed by intolerance of drugs(26.1%). Some study subjects took treatment from private doctor which form 20% of the study subjects.

DISCUSSION

Socio-Demographic factors

In the present study, the age group of the participants ranges from 16 to 55 years. Majority of the cases (86.7%) and controls (85.6%) were below 40 years of age. We did not find increase in risk of default in higher age groups. But the study by Chandrasekaran et al revealed a higher likelihood of default in age more than or equal to 45 years (15.4%) (AOR=1.9; 95% CI=1.2-3.0)[9]. A study by Chaterjee et al showed that the defaulters significantly increased (p<0.05) with age, the maximum being in the 45-59 years of age and declined thereafter.[10] The difference may be attributed to difference in study setting as well as difference in the study designs.

In this study, out of total subjects 50% are male and 50% were female. Among the defaulters male and females are 53.3% and 46.7% respectively. In a study at Hong-Kong , male sex was an important risk factors associated with default (OR=1.5; 95% CI= 1.1-2.1)[11] and a significant association also reported by other studies such as Colomet at Medagaskar[12], Daniel at Nigeria[12]. In Indian study by Jaggarajamma et al significantly higher proportion of defaulter were male (p < 0.01).[14,15]. Higher default rates were associated with being male (AOR=3.4; 95% CI=1.5-8.2) in a study by Santha et al.[16] The difference may be attributed to the difference in study designs used.

In our study, majority of the cases (53.3%) and controls (60%) were household workers. There was no statistically significant difference between occupation of cases and controls (p > 0.05). In a study in India by Balsubramanian et al being employed was the independent risk factors for default (AOR=1.7; 95%CI =1.1–2.4; p < 0.01).[17] But the unemployment was a risk factor independently associated (OR=4.44; 95% CI=2.23–8.86) with default outcome in a study at six Russian regions.[18] The difference may be attributed to the difference in the study settings.

In present study, study subjects were belonging to Below Poverty Line(BPL) i.e 80% and 20% were in Above Poverty Line(APL) and study subjects were similar in cases and controls both. The risk of being defaulter was 1.38 times more in BPL patient as compared to patient who was not below poverty line. While the other studies found default rate varied in different economic group. Chaterjee et al reported that with increasing family monthly income, the percentage of defaulters decreased uniformly at DTC Roing. But all defaulters in TMH Jamshedpur were high income group.[19]

In the present study, among the defaulters 26.7% were from joint family while in control group they constituted 73.3%. Odds of being defaulter was 0.13 (95% CI=0.22-1.46) among patients from joint family as compared to nuclear family and was found statistically significant(p <0.05). similar was seen in other studies Social support reduced the default outcome (OR 0.13; 95%CI =0.06–0.28) in a study at six Russian regions.[17]41 Family support is protective factor for default as seen in a study in Ethiopia (OR = 0.19, 95%CI= 0.08–0.46).[19].34

The literacy rate was higher in both, cases and controls 66.7% and 86.7% respectively with study subject studying upto higher secondary or more. Odds of being defaulter was 3.2 times more common among less the secondary level of education than that of higher secondary educated subjects in the present study and the difference was not statistically significant. In a study at Tiruvallur, 12.7% (OR=1.6; 95% CI=1.0-2.4) of defaulters were illiterate.[9] Illiteracy was the independent risk factor for non-adherence to DOTS after adjusting for confounding factors in study in south India by Gopi et al[21]

Personal factors

In present study, among cases 20% used to consume tobacco compared to none among controls. Tobacco users were more among cases than the controls. A study at Hong Kong by Chang et al showed that there was association between state of smoking and default (OR=3.00, 95% CI =1.41–6.39).[22] The difference may be due to small sample size, bigger study with more sample size is required.

In present study it was observed that 6.7% study subjects in case group and 20% in control group were consuming alcohol. It was insignicanct in determining the defaulters. Studies from India and other countries also showed significant association between defaulters and alcohol use. A study at Uzbekistan shows that individuals who consumed alcohol had a higher risk for default, OR 6.01 (95% CI=1.68 – 19.47).[23] Alcohol abuse was a risk factor independently associated (OR=1.99; 95% CI=1.04–3.81) with default outcome in study at six Russian regions[18]. The default rate was higher among alcoholics in a Swiss study.[24] In India, in a study by Jaggarajamma et al 24% (p<0.01) of drinker are defaulter.[14] The risk factors for default are alcoholism [75 of 274 (27%) vs 73 of 582 (12%); P<0.001] in another study in India at tiruvellur.[15] In a study by Santha T et al higher default rates was associated with alcoholism (AOR=2.2; 95% CI=1.3-3.6).[15] in another study by chandrahekaran V et al 17.1% (2.7;1.8-4.2) of defaulter were alcoholic.[9]

Most of the study subjects in cases were referred by health workers and others (80%) while the in controls they were 73% and there was no significance. HIGHER DEFAULT RATES WERE ASSOCIATED WITH DIAGNOSIS BY COMMUNITY SURVEY (AOR=2.1; 95%CI=1.2-3.6).[25] IN A STUDY BY CHANDRASEKARAN ET AL THE CASES IDENTIFIED AND REFERRED BY THE COMMUNITY SURVEY SHOWED 16.7% (1.8-1.1-3.0) DEFAULT.[9]

In present study it was seen that 26.7% of study subject in the cases group migrated and there were not migration in the control group study subject. Other studies such as one in Switzerland stated that default rate was significantly higher among immigrants in a study at Switzerland.[24] In a study in India migration of patient is one of the reasons for default among 24% of patients and is significantly higher among newly diagnosed patients as compared to previously treated Category II cases [21 of 61 (34%) *vs*. 4 of 43 (9%) p<0.001], and among patients who had resided at the given address for two years or less compared to more than two years (7 of 9 *vs*. 15 of 64; p<0.001).[13] A study from Bangalore city had reported that 20% of the defaulters had migrated under the DOTS based programme[25] While in cohort study at Tiruvallur 32% of defaulters were due to migration[9]

Diagnostic determinants

In present study 93.3% subject were defaulter in cases which were diagnosed from the government hospital. While in other studies HIGHER DEFAULT RATES WERE ASSOCIATED WITH DIAGNOSIS BY COMMUNITY SURVEY (AOR=2.1; 95%CI=1.2-3.6).[25] IN A STUDY BY CHANDRASEKARAN ET AL THE CASES IDENTIFIED AND REFERRED BY THE COMMUNITY SURVEY SHOWED 16.7% (1.8; 1.1-3.0) DEFAULT.[9]

In present study it was seen that old cases tends to become defaulter and odds is 4.3 and was found statistically significant(p<0.05). It was also seen in study at Hong-Kong, a history of past TB with default are significantly associated with default, (OR=8.2; 95% CI, 4.7-14.3)[11] and (OR=6.23, 95%CI=1.95–19.91)[22] as seen in two different studies respectively. This significant association(RR= 1.99, 95%CI=1.12–3.54, p = 0.035) is also seen in another study among Brazilian children by da Silva Oliveira et al.[26] Higher default rates are associated with history of previous treatment (AOR 2.8; 95%CI 1.6-4.9) in study by Santha et al.[25] It is independent risk factors for default (AOR=3.9; 95%CI=2.6–5.6; p ≤ 0.001) in a study by Balsubramanian et al.[17]

In present study it was seen that pulmonary cases were 46.7% and 80% in cases and controls respectively but was not found statistically associated with the defaulting Pulmonary TB is significantly associated with default [179 of 865 (21%) vs 7 of 73 (10%); p<0.05] in a study at Tiruvallur.[15]

In present study majority of the study subjects in both cases(60%) and controls(86.7%) were from category I. There was not association found among the study subjects when it came to category of treatment. While Category of patient is also a significant risk factor for default as in a study Jaggarajamma et al at Tiruvallur in which (38%), [p<0.001] were CAT-II.[15]

Treatment related factors

In the present study, among study subjects, 66.7% of cases and 6.7% controls were provided medicines by personnel from health department while rest were provided by the personnel from other departments such as anganwadi worker or other volunteers. The difference was statistically significant (p < 0.05). Present study observed that defaulters are less if the DOTS providers are not from the health departments but are volunteers(OR. 28). A study by Gopi et al in South India shows that non-governmental DOTS provider was the independent risk factors for non-adherence to DOTS after adjusting for confounding factors.[21]

In the present study all the study subjects suffered from the side effects and 40% of study subjects in both cases and controls groups were referred by self and remaining 60% study subjects in both cases and controls groups were referred by health workers. Different study in Hong-Kong on treatment side effects was associated with default(OR=13.30, 95% CI=3.23–54.79).[22] Medication side effect was significantly associated with defaulting (OR =4.20, 95%CI=1.51–11.66) in a study at Ethiopia.[20]

In present study, among the cases and controls 46.7% and 66.7% of the subjects were advised and counseled for regularity, duration and the side effects by doctor. As-sociation was not found statistically significant. While other study by Chatterjee et al shows that lack of motivation was significantly associated with default.[10]

Causes of defaulting

In the present study, the important reasons quoted by the defaulters are disappearance of symptoms (33.3%), intolerance to drugs (26.7%), and private treatment (20.0%). In a study by Chaterjee et al the indifference in improvement of symptom was reasons for defaulting. [10] In another study by Gopi et al, loss of wages was identified as an additional independent risk factor for default.[22]

CONCLUSION

To conclude, in the present study it was found that having nuclear family is one of the determinant for defaulting as continuous source of motivation is necessary for compliance of treatment by family members. It was also seen that old cases of TB were associated with defaulting this may be due to the drugs intolerance or due to the disappearance of symptoms or their adherence to treatment requires more counseling. Defaulting was also found significantly associated with DOTS provider who were from the health department this may be due to stigma attached to the disease where study subjects preferred to take medicines from other volunteers. Other determinants such as use of tobacco, migration and place of diagnosis of the study subjects were not studied properly due to less samples of study subjects. Further studies needs to be planned with more sample size so that their determinants can be looked closely for the association with defaulting. Important reasons quoted by the defaulters were disappearance of the symptoms(33.3%), followed by intolerance of drugs(26.1%), treatment from private doctor (20%) and others. The limitation of the present study should be kept in mind as it was a small scale study based on a small sample. Hence, further research is required to confirm our findings.

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