Original Article

Sources of Previous Anti-tubercular drugs exposure for patient registered in RNTCP as retreatment cases in District Anand, Gujarat

Varshney AM[1], Singh US[2], Kumar D[3]

[1]Assistant Professor, Subharti Medical College, Meerut, [2]Professor, [3]Assistant Professor, Department of Community Medicine, Pramukhswami Medical College, Karamsad, Gujarat.

Abstract

Background: *M .tuberculosis* is an ancient infectious killer that still remains one of the leading causes of death worldwide. India alone accounts for an estimated one fifth of all TB and half of the retreatment TB cases worldwide.

Objective: To obtain information regarding treatment practices among retreatment cases of TB patients and to identify socio-demographic factors leading to default or treatment failure or relapse.

Methodology: A cross sectional descriptive study was conducted in two TB units of district Anand, Gujarat using pre-tested questionnaire in Gujarati language. A sample size of 100 patients was selected to estimate 50% prevalence of Non-RNTCP treatment with allowable error of 20%.

Results: 60% of retreatment cases were of relapse, 37% of participants were of treatment after default, others 9% and 3% of treatment failure cases. 67% of participants received their treatment from Government health facility (RNTCP). Side effects were the commonest reason for defaulting initial treatment. Taking treatment from a private physician was associated with increased risk for side effects as well as defaulting during initial treatment. Socio-demographic factors like age, sex, religion, socio-economic status, occupation were similarly distributed between the default and retreatment groups.

Conclusions: Efforts need to be made towards the support, supervision and follow up of the patients in private sector. Patients must be educated about possible adverse drugs and to provide support to overcome them. Reasons for the large number of relapse TB cases from those already treated under the national programme require detailed investigation.

Key words- RNTCP, Retreatment cases, Tuberculosis, Private practitioners.

Introduction:

M. tuberculosis is an ancient infectious killer that still remains one of the leading causes of death worldwide. Tuberculosis (TB) has been reported as one of the most important public health problems by all regions of World Health Organization. There were an estimated 9.4 million incident cases TB globally which is equivalent to 137 cases per 100000 population[1]. Most of the estimated number of cases in 2009 occurred in Asia (55%)[1]. The five countries with the largest number of incident cases in 2009 were India (1.6–2.4 million), China (1.1–1.5 million), South Africa (0.40–0.59 million), Nigeria (0.37–0.55 million) and Indonesia (0.35–0.52 million)[1]. India alone accounts for an estimated one fifth (21%) of all TB cases worldwide, and China and India combined account for 35%. In 2009, 622,342 (10%) of the 6.12 million of global total TB notifications were re-treatment TB cases. India, however, disproportionately accounts for nearly half of re-treatment TB cases notified globally, with 289,756 notified re-treatment cases in 2009[1]. The notification rate of re-treatment cases has increased by 67% over the past 12 years; from 15 per 100,000 population in 1999 to 25 per 100,000 population in 2010[2].There are 29% of retreatment cases out of all smear positive cases in Gujarat[3]. There were an estimated 440000 cases of multi-drug resistant TB (MDR-TB) globally in 2008 .The four countries that had the largest number of estimated cases of MDR-TB in absolute terms in 2008 were China, India , the Russian Federation and South Africa [1]Retreatment group is extremely diverse, with patients having been treated with varying durations and anti-TB regimens. Retreatment patients may have been treated many years prior or may have only recently failed or defaulted,

Address for Correspondence:
Amit Mohan Varshney, Assistant Professor, Subharti Medical College, Meerut.
Email: dramitmv14@gmail.com

and may have been treated by the private or public sectors (or both) in the past. Among patients being retreated for TB because of initial treatment failure, default from initial treatment, or relapse following initial treatment, drug resistance is common and retreatment outcomes inferior[4,5]. Present study was conducted to obtain information regarding treatment practices among retreatment cases of TB patient and to describe the socio-demographic profile, previous treatment history of the re-treatment cases and to identify risk factors for default, case failure, relapse.

Methodology:

A cross sectional descriptive study was conducted in two TB units (TUs) Petlad and Anklav of district Anand, Gujarat during one year (April 2009- March2010). By simple random sampling method, out of four TU, two TU were selected. A List of registered retreatment cases were taken from District TB Centre (DTC) Petlad and 100 patients from nearby villages of the two TUs were selected.

We assumed that 50% of the re-treatment cases would have previously been treated under Revised National TB Control Programme (RNTCP). A sample size of 100 patients was selected to estimate 50% prevalence Non-RNTCP treatment with allowable error of 20%. Sample size = $4PQ/L^2$ = 4 X 50 X 50 / 10 X 10 =100.100 participants have been included in the study. 50 participants were selected from Petlad TU & 50 from Anklav TU.

Patients who were on retreatment regimen (registered as failure, relapse, treatment after default) at the two TUs under the study during the period of April 2009-March 2010 and aged 15 and above were included in study. Patient who did not give consent, died but registered as retreatment cases and who has migrated to another area were excluded from the study. After collecting the name and address of retreatment cases registered under RNTCP from DTC Petlad, they were approached at their addresses and data collection was done through individual interviews. A pretested, structured and coded questionnaire was used while conducting the interview to record the responses of the participants. The interview started only after the participant signed the informed consent form in Gujarati. No one disagreed for the participation in the study. The master chart prepared in Microsoft Excel was converted to a Statistical Package For Social Sciences (SPSS) data file for analysis The analysis was done using the software SPSS for the Windows Version.15.0. Frequency tables were prepared for the various nominal variables. For the continous variable (viz .age, family size,) median and mean with 95% confidence intervals were calculated .To find out the association between two categorical variables, Chi-square test was applied. Wherever the expected frequency of variable was less than five Fisher's exact test was applied.

Results:

There were 100 participants in total of which 37% were defaulters during initial treatment. The mean age was 42 (39.4-44.4) years. The demographic profile of the participants is shown in table 1. There were 65% male participants and 35% female. 53% of the participants were illiterate , 81% were married, 74% were Hindu.21% of the participants were unemployed , 55% earned their living by doing unskilled work and monthly income of 69% of participants was less than Rs.2500 per month. 47% of the participants were addicted to smoking and another 18% to chewing tobacco.

72% of participant had cough, 69% of participants presents with fever, 19% with chest pain, 24% with loss of weight and 7% had participants develop night sweat when they initially took the treatment. Majority of participants had presented with more than two symptoms commonly with cough and fever. 52% of participants had first time consulted private physician for their illness and 48% from Government physician. For the purpose of diagnosis, sputum microscopy for Acid Fast Bacilli (AFB) was conducted at Government health facility in 61% of participants and 39% from private health facility. Among all participants 67% received their treatment from Government health facility. Side effects were the commonest reason for defaulting initial treatment. Other reasons for initial default are shown in figure 1. Taking treatment from a private physician was associated with increased risk for side effects as well as defaulting during initial treatment (Table 2 and 3).

Table 1. Demographic profile of the participants

Demographic characteristic	Frequency	Demographic characteristic	Frequency
Age distribution		**Marital Status**	
Age≥19	8 (8%)	Never married	19 (19%)
Age 20-29 years	7 (7%)	Married	80 (80%)
Age 30-39 years	20 (20%)	Widowed	1 (1%)
Age 40-49 years	34 (34%)	**Religion**	
Age 50-59 years	21(21%)	Hindu	76 (76%)
Age≤60 years	10 (10%)	Muslim	24 (24%)
Family Structure		**Addictions**	
Joint	23 (23%)	None	34(34%)
Nuclear	49 (9%)	Smoker	47 (47%)
Three generation family	28 (28%)	Oral tobacco	18 (18%)
		Alcohol	1 (1%)

Figure 1. Reasons for defaulting initial therapy among the participants (N=37)

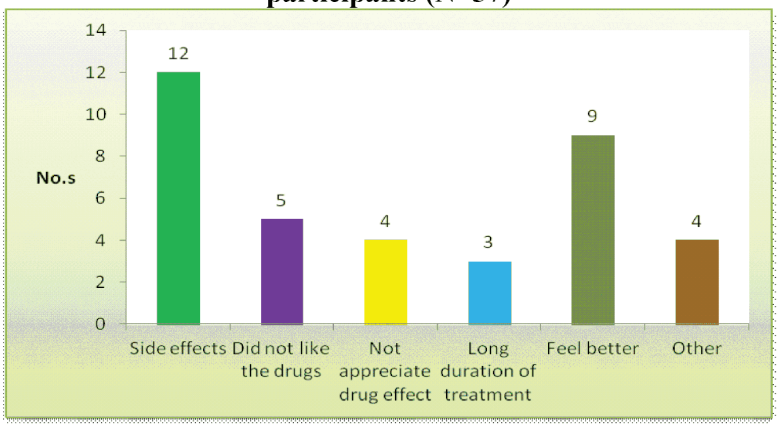

Table 2. Association between outcome of initial Anti tubercular therapy and treating physician

Physician	Type of Cases		Total
	Relapse &Failure	TAD*	
Private	12 19.0%	21 56.76%	33 33.0%
Government	51 81.0%	16 43.24%	67 67.0%
Total	63 100.0%	37 100.0%	100 100.0%

Chi-square =14.9, df =1, p=0.0001,*Treatment after default

Table 3. Association of treating physician and side effects among Treatment after default participants during initial Anti tubercular therapy.

Side effect	Private Physician	Govt. Physician	Total
Yes	10 47.6%	2 12.5%	12 32.43%
No	11 53.4%	14 87.5%	25 67.57%
Total	21 100%	16 100%	37 100%

Chi-square (Fisher's exact) =3.63, df =1, p=0.05

Discussion:

Present project is a cross sectional descriptive study designed to explore the history of previous treatment of patients who have been registered under retreatment category of RNTCP. The demographic profile and various factors which contributed in starting the treatment under retreatment category of the participants were also studied. The age and sex distribution of participants in our study was similar those reported in other studies from India[6,7]. In our study, 60% of retreatment cases were of relapse, 28% of participants were of TAD (Treatment after default), 9% were others and 3% of treatment failure cases. Study carried out in Gujarat showed that there was 42% of relapse cases in retreatment cases, and 53% was TAD & others, 4%were treatment failure[8]. In a study conducted in Delhi, failure rate was found 3.4% cases[9].

Relapse is the commonest cause of administering retreatment regimen with Category II in up to 65.61 % of cases[10]. Socio-demographic factors like age, sex, religion, socio-economic status, occupation were similarly distributed among the default and retreatment groups.

Among the defaulter participants most common cause of non-compliance was side effect in 33% of them followed by feeling better in 24% of the participants. A study conducted in Meerut by Mittal Chaya *et al* (2011) showed that 43% of participants defaulted because of side effects followed by 15% of cases because of improvement in symptoms[11]. A study conducted in Anand District in 2006, observed that majority 63.2% of patients on DOTS stopped treatment because of toxicity of drugs. The other reasons were feeling better during treatment 15.8% and lack of knowledge about various aspects of TB and its treatment 10.5%[12]. Side-effect had a significant relationship with treatment interruption ($p<.05$), thus every efforts should be made to educate patients in such a way to reduce those unwanted side-effects. A study from Bihar and West Bengal reported that improvement in symptoms (40% and 56%), intolerance to drugs (20% and 9%) following good patient education[13]. All efforts must be made to educate patient about possible adverse drugs and to provide support to overcome them.

Among all participants those who received treatment from private practitioners had more proportion of side effects. 33% of participants have started their treatment from private practitioner in our study. Also the default proportion was more among those treated at private health facilities. Study carried out in Gujarat, showed that 44% of participants took their treatment from Non RNTCP sources[14]. In this study that more proportion of participants who completed their treatment had taken the treatment from Government physician and who did not complete their treatment more proportion of them started their treatment from a private physician which is statistically significant. 64% of patients who had the treatment from the non RNTCP sources had defaulted. Other Indian studies have also documented a higher defaulter rate among patients managed in the private

health facilities compared to the public health facilities[15, 16]. Most of the private practitioner do not follow RNTCP guideline & do not have any strategy to follow up the patients so there are more chances of getting defaulted from the treatment.

Efforts need to be made towards the support, supervision and follow up of the patients in private sector because follow up mechanism is very poor in this set up. Private practitioners should be called for RNTCP training programmes to update knowledge and strategies time to time. In addition, reasons for the large number of relapse TB cases from those already treated under the national programme require detailed investigation. Future prospective studies should seek to investigate the roles of other important risk factors that we could not assess in this retrospective analysis. Research to understand the challenges faced by patients and providers should be under taken.

Limitations-

-Due to small sample size results of the study can not be generalized.

-It is a dissertation work so allowable error was taken more to reduce sample size so that dissertation work could be completed in time with limited resources.

Acknowledgement:

I extend my sincere thanks to operational research committee,RNTCP Gujarat, faculty and staff of PSMC Karamsad specially Mr. Maheshbhai Parmar for his kind support during the data collection of this project.

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