A Study on Prevalence of Initial Defaulters among Sputum Smear Positive TB Patients and Their Reasons under RNTCP in Jamnagar District, Gujarat, India

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Abstract :

   Introduction: The smear positive TB patients who aren't put on treatment after diagnosis are called 'Initial defaulters'. Annually, many patients are diagnosed with TB under RNTCP, but many of them don't return to the program after diagnosis. This study is an attempt to identify reasons of such initial defaulting. The objective of the study is to measure prevalence of initial defaulters, its reasons and its association with socio-demographic factors. **Method :** It's a cross-sectional study covering all TB Units of Jamnagar district, and all TB patients diagnosed between 1st January, 2012 and 31st December, 2013. They were screened for initial defaulting. Data collected and field visits planned between 1st January 2016 and 31st September 1016. **Results:** Reported initial default rate was 5.12%, but actual default rate was only 2.39%. Initial defaulting rate was higher in Jamnagar TU compared to other TUs and in males compared to females. About 74.36% patients started anti-TB treatment from private institute. **Conclusion:** There was a discrepancy between reported ID patients and actual ID patients, as many were put on later in subsequent quarters. Majority TB patients started private treatment. Defaulting rate was higher in middle aged patients.

Keywords : Initial Default, RNTCP, Sputum Positive Cases, TB, TB Units

Introduction :

India is the highest TB burdened country in the world in terms of absolute number of incident cases occurring every year. It accounted for one-fourth of estimated global incidence of TB cases in 2013. [1] To overcome this enormous burden of TB, the DOTS strategy was introduced in the country in 1997 under Revised National TB Control Program (RNTCP).

The program is accountable for the outcome of every patient put on treatment and uses a standardized recording and reporting system. The key indicators of the program are monitored at every level of health system. [2] Patients diagnosed with smear-positive tuberculosis who do not initiate treatment (pre-treatment loss to follow-up or initial default) represent an important failing in the provision of care. [3] Bringing these patients into care could reduce tuberculosis transmission to others. [4]

While several studies have reported on initial default, there is little information about the extent of this problem globally. [5] The present study tries to identify reasons of such initial defaulting among newly diagnosed sputum smear positive TB patients under RNTCP.

Aims and Objectives:

1. To find out prevalence of initial defaulters among newly diagnosed sputum smear positive TB patients of Jamnagar district.

2. To find out the possible reasons of initial default among TB patients under RNTCP in the district.

Method :

This was an analytical cross-sectional retrospective study covering all TB patients of all TB units of Jamnagar district, diagnosed at all Designated Microscopic Centres (DMCs) between 1ˢᵗ January, 2012 and 31ˢᵗ December, 2013.

Initial defaulters or diagnostic defaulters are defined as TB patients diagnosed as sputum smear positive tuberculosis at accredited Designated Microscopic Centres (DMCs) by Revised National TB Control Program (RNTCP) but not registered under the program and not put on standard anti-tuberculosis treatment.

TB registers and Laboratory registers of all TB Units of Jamnagar districts of both calendar years (2012 and 2013) were cross-checked to find out whether they were registered and put on treatment or not. If a TB patient was diagnosed, but not registered then we inquired whether he/she was initial default or not, by tracing contact details and address of the patient. Such TB patients were visited at their residences and asked whether any TB official contacted the patient, home visit paid etc. Then TU wise line- listing of such patients was carried out. Duration of data collection was from 1ˢᵗ January 2016 to 31ˢᵗ September 2016.

Inclusion Criteria:

All newly diagnosed sputum smear positive TB patients diagnosed at all DMCs of all TB Units (TUs) of Jamnagar district, registered from January 1ˢᵗ, 2012 to December 31ˢᵗ 2013. (Including all TB patients transferred from one TU to another TU within district).

Exclusion Criteria:

i.   All sputum smear negative and MDR TB patients diagnosed at all DMCs and TUs of Jamnagar district.

ii. Patients died after diagnosis before he/she was put on treatment.

iii. Patients reported as ID initially in one quarter, but put on treatment later.

iv. Patients moved out of district /state (Transferred out) after diagnosis.

Data collection Techniques and Tools :

Cases were interviewed by a proforma containing pre-tested semi-structured questionnaires which included questions about socio-demographic profile, past history of treatment with tuberculosis, reasons for not starting prescribed treatment etc. Training of field investigators included instructions and orientation about how to collect data using pre-tested proforma, importance of the study and orientation about the formats used.

Data Analysis: Data were entered and analysed using Microsoft Excel sheet, 2007. Descriptive statistics such as frequency, mean, standard deviation, median, minimum and maximum, etc were calculated as appropriate. Comparisons between groups were made using the Chi-square test or Fischer's exact test as appropriate for qualitative variables. Level of significance was set at 95%.

Ethical Considerations :

We obtained ethical clearance certificate from the Institutional Ethics Committee of M.P. Shah Govt. Medical College, Jamnagar after sanctioning the research project. The purpose for seeking information was explained in detail to every eligible patient and TB officials and TB workers and informed consent was obtained prior to interview. The data collected was presented as an aggregate and was not linked to any individual patient in the study. The data obtained during the study was securely held and confidentiality was maintained at every level.

Results :

Out of 167 patients identified and reported as Initial defaulters in their respective or subsequent quarters in years 2012 and 2013, we observed that 89 patients were either actually put on treatment in the subsequent quarter of the year or had died. Remaining 78 patients were those that had not been put on anti-TB treatment. Out of these 78 patients, We could trace only 39 patients In our study, thus 50 % patients could not be traced. (Figure 1)

Figure 1: Flow chart showing proportion of initial defaulters
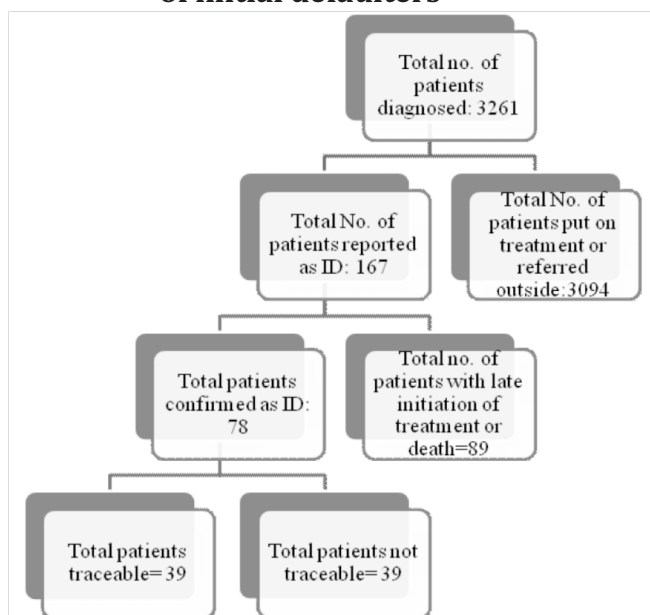
Out of total 39 traced patients, majority of them (69.23%) belonged to Jamnagar TU. (Table 1)

Out of total 39 traced patients 53.85% patients were from urban area and 58.97% patients were above 45 year age.(Table 2)

The mean age of the interviewed ID patients was 47.68 years with Standard Deviation 14.71 years. Past history of treatment with anti-tuberculosis drugs has not been found to be associated with initial defaulting, as about 58.33% patients had not revealed any treatment with tuberculosis drugs in the past. Regarding the literacy status of the patients, more than one-forth (28.20%) of patients had their study up to primary schoolings, 23% were illiterate, whereas same proportion of patients had studied either higher secondary or more. When we inquired whether any TB worker visited their homes, about 72% patients replied that a TB worker visited their homes. (Table 3)

Out of total 39 traced patients, when asked about reasons for non-initiation of treatment, about 29 % patient said they started AKT (anti-tuberculosis therapy) from private providers, and 28% not started treatment because they felt the treatment course too lengthy(Figure 2).

**Table 1: TU wise distribution of ID patients interviewed.**

Name of TU	Total no. of ID patients interviewed No. (%)
Jamnagar	27 (69.23)
Dhrol	5 (12.82)
Khambhaliya	7 (17.95)
Lalpur	0 (0.00)
Total	39 (100.00)

Table 2: Age distribution of cases among rural and urban communities

Age distribution	Urban No. (%)	Rural No. (%)	Total No. (%)	Statistics
15-45 years	8 (50.00)	8 (50.00)	16 (41.03)	OR=0.77
>45 years	13 (56.52)	10 (43.38)	23 (58.97)	(0.18-0.34)
Total	21 (53.85)	18 (46.15)	39 (100.00)	χ^2=0.16
				P= 0.69

Table 3: Socio-demographic profile of Initial defaulters in Jamnagar district

Character	Jamnagar (n=27)	Dhrol (n=5)	Khambhaliya (n=7)	Average (n=39)
Mean Age in Years (SD) (95% CI)	44.55 (17.49) (37.63-51.47)	45.4 (19.73) (20.90-69.89)	53.10 (19.19) (35.35-70.84)	47.68 (14.71) (42.91-52.49)
Past History of TB treatment[No. (%)]	9 (33.34)	1 (20.00)	1 (14.28)	11 (41.67)
Locality [No. (%)] Urban Rural	21 (77.77) 6 (22.23)	0 (0.00) 5 (100.00)	0 (0.00) 7 (100.00)	21 (53.85) 18 (46.15)
Home visit by health workers [No. (%)] Yes No Don't know	19 (70.37) 3 (11.11) 5 (18.51)	4 (80.00) 1 (20.00) 0 (0.00)	5 (71.42) 2 (28.58) 0 (0.00)	28 (71.79) 6 (15.38) 5 (12.82)
Literacy Status [No. (%)] Illiterate Primary Secondary Higher Sec & above	5 (18.51) 7 (25.92) 6 (22.22) 9 (33.33)	1 (20.00) 2 (40.00) 2 (40.00) 0 (0.00)	3 (42.85) 2 (28.57) 2 (28.57) 0 (0.00)	9 (23.07) 11(28.20) 10 (25.64) 9 (23.07)

Figure 2. Reasons for non-initiation of treatment under RNTCP (Multiple responses) (n=39)
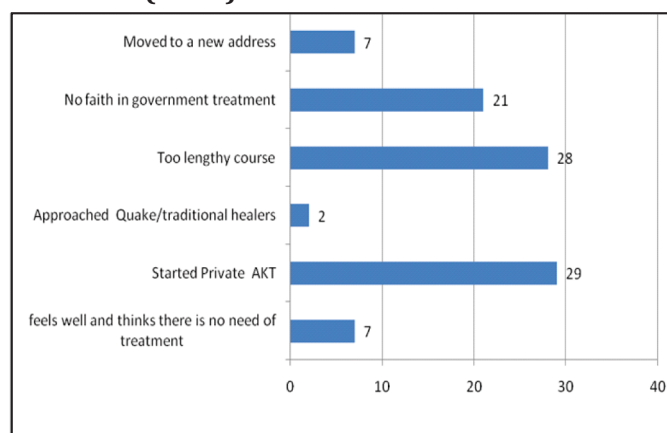
Discussion:

As many patients might have moved to new address or region and have changed their contact details, we were able to trace 39 TB patients that were diagnosed at DMCs of Jamnagar district, but failed to put on treatment under RNTCP. In a South Indian Study [6], of total reported initial defaulters, 47.5% had been actually placed on RNTCP treatment, and were incorrectly reported as initial defaulters due to non-reconciliation of records of patients referred for treatment elsewhere in the same district and delayed treatment initiation or registration for treatment in the subsequent quarter.

Nisar Ahmed Rao et al in his study in Pakistan in year 2007-08 reported an alarmingly high initial default rate which was as high as 27.67%. The most common reason being dissatisfaction with services rendered at the clinic (33.33%).[7] Another study by Gopi PG et al in South India reported about 14.9% initial default rate, and major reasons for defaulting were loss of wages, dissatisfaction with services of health care providers and disease related issues like feeling well or too ill.[6]

A study by Buu TN et al in Vietnam reported 8.3% initial default rate, with 79.5% defaulting due to issues related to health care provider.[8] A most recent study from South Africa reported initial default rate of 17%.[9]

We found many patients' incomplete addresses in address column of TB Laboratory registers of TU. And phone numbers were also missing or incorrect for many patients. In a study in Pakistan,[7] 11.29% patients could not be traced. Sai Babu et al in Andhra Pradesh reported a high rate (51%) of untraceable defaulters in his study. [10] In our study, about 74.36 % patients were taking treatment from private service providers. In a study by Sai Babu et al, initial default rate was higher in urban areas compared to rural areas.[10] Moreover, they observed that about 5.5% of ID patients were taking treatment outside the program including private practitioners.

In a study by R.Balasubramanian in South India, [11] rate of initial defaulters was equal among both males and females, and among smear positive patients diagnosed, rate of initial default did not differ by age or sex.

In our study, almost four-fifth of interviewed patients were males. Thus, we can say that males may undergo initial defaulting more than females. It may be due to sampling error as more male patients might have been traced and interviewed. We did not calculate sex specific default rate as we did not have denominator in terms of total number of male and female patients enrolled during the study period. In a study in Pakistan in 2009, observers found proportion of initial default among males more than females.[12]

Past history of treatment with anti-tuberculosis drugs has not been found to be associated with initial defaulting, as about 58.33% patients had not revealed any treatment with tuberculosis drugs in the past. Recently in year 2016, Government of India has declared TB a notifiable disease, which is an appreciable step and will help supplement missing data about TB detection and cure rate. Dewan et al has proved that Public-private joint activities were associated with improved case notification, while maintaining acceptable treatment outcomes [13].

Conclusion:

The initial default (ID) rate as reported by the program was 5.12% but actual ID rate was 2.39% as many patients were put on treatment later in the subsequent quarter, so they were erroneously reported as ID patients. Thus, there was a gap between reported ID patients and actual ID patients. The majority of patients interviewed belonged to Jamnagar urban TB Unit.

The major reason for initial defaulting was initiation of treatment from private institutes or clinics, followed by lengthy duration of treatment.

Incomplete address and contact details taken by Senior Treatment Supervisor (STS) and Senior TB Laboratory Supervisor (STLS) led to loss of many patients, who could have been traced and interviewed.

Recommendations:

Initial default or diagnostic default is a vital issue for better control of TB in the Revised National TB Control Program. Medical Officer (MO) or STS should regularly match laboratory registers with TB registers to identify and trace ID patients as early as possible, before they become untraceable. Reasons behind this behaviour should be sought and all attempts should be focused to bring these patients back in the program.

MO/ District TB Officer (DTO) should instruct STS/STLS to note correct and complete contact details of all TB patients, so that they can be easily traceable anytime if went missing from the system.

Significance of initial defaulting in the program should be given due importance in the training of STS and STLS before their recruitment and even during their refresher training. MO/DTO should ask for any ID case to the STS/STLS and if present, all attempts should be made to put him on treatment as early as possible.

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