Treatment outcome of TB patients in a district of north India: a three year study

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Original Article

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Abstract

Background

Tuberculosis (TB), still remains a public health problem of great concern. It was estimated that 8.6 million people developed TB and 1.3 million died from it. India has the highest TB burden in the world. DOTS ensures high cure. Therefore the present study was planned to assess the outcome of DOTS treatment among pulmonary and extra pulmonary TB patients reporting at DOTS centers of the district

Materials and methods:

A record based study using the routine program data of Revised National Tuberculosis Control Programme was conducted in one of twenty two districts of state of Punjab, situated in northern India. Records of all the patients registered from 1st January 2011 till 31st December 2013 were analysed using descriptive statistics. The differences between proportions were compared using tests of significance.

Results:

A total of 2571 new cases of Tuberculosis were registered during the study period of three years, out of which 44.8%, 22.9% and 32.3% were diagnosed to be new smear positive, smear negative and suffering from Extra pulmonary tuberculosis (EPTB) and a total of 369 retreatment cases were registered. Cure rates were highest among patients suffering from EPTB when compared to those of smear positive and smear negative. The proportion of defaulters among smear positive failures was highest, followed by smear positive after default and lowest in smear positive relapses.

Conclusion

Cure rates were higher among EPTB cases whereas default rate was more among patients suffering from pulmonary TB. Therefore higher level of motivation of cases by health and non-health personnel is required as untreated or under treated pulmonary TB cases are responsible for transmission of the disease in the community. Default rates could be decreased by concrete efforts in the form of strict supervision and monitoring.

Key words: Directly observed therapy (DOT); Patient Cured;

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Treatment completed; Treatment Defaulter; Treatment Failure.

Background

Tuberculosis (TB), which is caused by bacteria belonging to the mycobacterium tuberculosis complex is one of the oldest diseases known to affect human beings. It can affect lungs (pulmonary TB) as well as involve other organs too (extra pulmonary TB) [1]. TB is still regarded as a major public health problem and its magnitude can be assessed from the fact that in year 2012, 8.6 million people suffered from TB and as much as 1.3 million deaths resulted because of TB. The South-East Asia (29%), African (27%) and Western Pacific (19%) regions majorly contribute to the burden of the disease[2]. India has maximum of TB cases in the world (23% of the global incidence of TB cases)[2].

Since the launch of the Directly Observed Treatment Short course strategy (DOTS strategy) for cure, care and control of TB by the World Health Organization worldwide in 1995, and Stop TB strategy in 2006, 56 million people have been successfully treated for TB and has saved 22 million lives approximately [2].

RNTCP has been launched with a goal to cure TB as well as decrease its transmission to the minimum among the community. Multiple medications are given to patient for a period minimum 6 months which is a challenge for both patients and providers[3]. Non-adherence to treatment has led to increase in treatment failure, relapse, drug resistance (acquired), and increased duration of infectiousness of patients [4, 5].

Several international organisations have recommended DOTS strategy as a standard for treatment care as well as for improving treatment adherence. In DOTS strategy all the patients receive each dose of anti TB medications under observation[6,7]. DOTS maximises the likelihood of completion of therapy because of its patient oriented approach[8].

DOTS ensures high cure rate through its 3 components namely appropriate medical treatment, supervision, and motivation by health worker and monitoring of the disease status by health personals. Therefore present study was planned to assess the outcome of DOTS treatment among TB patients reporting at DOTS centers of the district.

Material and Methods

Study Design & the Participants: This was a record based study conducted in one of the twenty two districts of state of Punjab located in northern India.

Data Collection: The routine program data of RNTCP was used. Records of all the patients registered for TB treatment from 1st January 2011 till 31st December 2013 were analysed. The data extraction on treatment category and TB treatment outcome was done from the records. The patient wise data on individual characteristics was not available as the data which flows in from DOTS units in the periphery to district headquarters, lacks patient wise data on individual characteristics. Only the summary of numbers of patient's categories by outcome is available.

Inclusion criteria: All the patients put on DOTS treatment during the study period.

Exclusion criteria: Any patient registered before and after the study period.

Sample size: 2571 tuberculosis patients registered for DOTS treatment during the study period constituted the sample size.

Outcome Variable: As per the WHO Stop TB Program the following TB outcomes were considered: Cured, Treatment Completed, Treatment success, Failure and Default and there definitions as per RNTCP are as follows: (1) "Cured": Any sputum smear positive (sm+ve) patient in the beginning, has completed treatment and two sputum smears on different occasions including one at the completion of the treatment are tested to be negetive. (2) "Treatment completed": For smear positives, after the completion of treatment, if sputum examination could not be conducted, the patient was categorized as treatment completed. For smear negative or EPTB, any patient who receives complete treatment and does not become smear positive at the end of the treatment was also categorised as treatment completed. (3) "Treatment Success": Cured plus treatment completed are together categorised as "Treatment success". (4) "Failure": Any patient who remains smear positive even at the end of five months or more of starting the treatment. (5) "Defaulter": Any patient who stops/interrupts treatment for more than two months consecutively and (6) "Died": Any patient who dies during the treatment period[1].

Ethical committee approval: Ethical approval was obtained from Institutional ethical committee.

Data management & Statistical analysis:

Data was compiled using Microsoft excel 2013. Descriptive analysis was done, and relevant proportions were calculated. The differences between proportions were compared using tests of significance.

Result:

A total of 2571 cases of Tuberculosis were registered during the study period of three years, out of which 44.8% were new smear positive, followed by 32.3% who were suffering from EPTB and 22.9% were smear negative. As far as registration of retreatment cases was concerned, a total of 369 cases were registered. Maximum of these i.e., 261 (70.7%) were smear positive relapses, followed by smear positive defaulters (20.9%) and minimum i.e., 31 (8.4%).

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Table 1: Treatment outcome among new cases of Tuberculosis (2011-2013)

Year	Cured	Died	Failure	Default	Total
New Smear Positive cases					
2011	345 (94.1)	9 (2.4)	6 (1.6)	7 (1.9)	367 (100.0)
2012	350 (93.1)	11 (2.9)	6 (1.6)	9 (2.4)	376 (100.0)
2013	378 (92.6)	21 (5.2)	4 (1.0)	5 (1.2)	408 (100.0)
Total	1073 (93.2)	41 (3.6)	16 (1.4)	21 (1.8)	1151 (100.0)
Smear Negative Cases					
2011	189 (97.4)	2 (1.0)	1 (0.5)	2 (1.0)	194 (100.0)
2012	153 (93.3)	3 (1.8)	2 (1.2)	6 (3.7)	164 (100.0)
2013	221 (95.7)	7 (3.0)	0 (0.0)	3 (1.3)	231 (100.0)
Total	563 (95.6)	12 (2.0)	3 (0.5)	11 (1.9)	589 (100.0)
Extra Pulmonary TB					
2011	253 (99.6)	0 (0.0)	0 (0.0)	1 (0.4)	254 (100.0)
2012	282 (96.2)	5 (1.7)	0 (0.0)	6 (2.1)	293 (100.0)
2013	279 (98.2)	4 (1.4)	0 (0.0)	1 (0.4)	284 (100.0)
Total	814 (97.9)	9 (1.1)	0 (0.0)	8 (1.0)	831 (100.0)

Table 1 shows the treatment outcome of new cases over the study period. Among the new smear positive cases of tuberculosis the cure rate was 94.1% in year 2011 and a decreasing trend was seen in year 2012 (93.1%) and 2013 (92.6%). The failure rate over three years has been the same (1.6%, 1.6% & 1.0% in year 2011, 2012 & 2013). The deaths attributing to tuberculosis have increased marginally from 2.4% in year 2011 to 5.2% in 2013. The defaulters have shown a decrease by half from 2012 to 2013 (9 cases vs 5 cases) which could be attributed to increasing awareness and treatment compliance of the patients put on DOTS.

Opposite results were seen in new smear negative cases where the cure rates have shown a reverse trends pertaining to cure rates. In year 2011 cure was obtained in 97.4% of patients put on DOTS but decreased to 93.3% in 2012 but a slight increase was seen in 2013 (95.7). As far as overall cure rate were slightly higher in smear negative (95.6%) as compared to smear positive (93.2%). The deaths in retreatment cases have also shown a rise by three fold. No case of failure to DOTS treatment was reported in 2013 of smear negative case and all three years among EPTB cases. Cure rates were highest among patients suffering from EPTB (97.2%) when compared to those of smear positive (93.2%) and smear negative (95.6%).

Table 2: Treatment Outcome of Retreatment cases of different categories (Smear positive Relapses, Failure & after default)

Year	Cured	Died	Failure	Default	Total
Smear positive Relapses					
2011	56 (94.1)	5 (2.4)	3 (1.6)	3 (1.9)	67 (100.0)
2012	89 (93.1)	1 (2.9)	1 (1.6)	5 (2.4)	96 (100.0)
2013	80 (92.6)	6 (5.2)	6 (1.0)	6 (1.2)	98 (100.0)
Total	225 (86.2)	12 (4.6)	10 (3.8)	14 (5.4)	261 (100.0)
Smear Positive Failure					
2011	6 (75.0)	0 (0.0)	0 (0.0)	2 (25.0)	8 (100.0)
2012	8 (80.0)	0 (0.0)	0 (0.0)	2 (20.0)	10 (100.0)
2013	8 (61.5)	2 (15.4)	1 (7.7)	2 (15.4)	13 (100.0)
Total	22 (70.9)	2 (6.5)	1 (3.2)	6 (19.4)	31 (100.0)
Smear positive after Default					
2011	23 (79.3)	1 (3.4)	3 (10.3)	2 (6.9)	29 (100.0)
2012	6 (40.0)	3 (20.0)	4 (26.7)	2 (13.3)	15 (100.0)
2013	25 (75.7)	5 (15.2)	2 (6.1)	1 (3.0)	33 (100.0)
Total	54 (70.1)	9 (11.7)	9 (11.7)	5 (6.5)	77 (100.0)

The treatment outcome of retreatment cases is shown in table 2. Overall cure rate of 86.2% was seen in smear positive relapse cases put on DOTS, which was comparatively higher that those cured after smear positive failure (70.9%) and smear positive after default (70.1%). A decreasing trend of cure was seen in year 2011, 2012 and 2013 among smear positive relapses (94.1%, 93.1% & 92.6%) and smear positive failure (75.0%, 80.0% & 61.5%). Deaths among retreatment cases have also increased over the study period in all the three categories. The proportion of defaulters among smear positive failures was highest (19.4%), followed by smear positive after default (6.5%) and

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lowest in smear positive relapses (5.4%). A proportionate decreasing trend was seen among smear positive failures who defaulted the retreatment over three years of study period (2011-2013). Maximum proportion of failure to retreatment was seen among smear positive after default (11.7%) and somewhat equal proportions of failure among smear positive relapses (3.8%) & smear positive failure (3.2%).

Table 3: Comparison of treatment outcome among new cases and retreatment cases.

Treatment Outcome	New cases	Retreatment cases	P value
Cured	2450 (95.3)	301 (81.6)	<0.01
Death	62 (2.4)	23 (6.2)	< 0.001
Default	40 (1.6)	25 (6.8)	< 0.001
Failure	19 (0.7)	20 (5.4)	<0.001

The table 3 shows the comparison of treatment outcome among new cases and retreatment cases. The cure rate was significantly higher among new cases whereas the proportion of deaths, default and failure among the patients put on DOTS was significantly higher among the retreatment cases.

Discussion

New cases v/s Re-treatment cases:

A total of 2940 cases of TB were registered during the study period out of which 87.4% were new cases and 12.6% were those put on retreatment due to various reasons (relapse:8.9%, Failure: 1.1% and treatment after default: 2.1%). 66.7% of new cases were found to be suffering from pulmonary TB. Quite similar results were reported by a study carried out at a TB unit (TU) of Howarh district, West Bengal in 2001 where 78.3% were new cases out of which 67.1% were suffering from pulmonary TB. Overall 2.1% were relapse, 1.1% failure, 3.8% treatment after default & 14.7% were other categories[9]. Somewhat similar results were reported in a study conducted by TRC, Chennai at a rural TB unit in Thiruvallam district of southern India during 2006 which showed that 42% were new sputum positive, 45% were new sputum negative and 13% were retreatment cases[10]. This portrays that proportions of type of TB patients being reported from various regions of the country are somewhat similar therefore this seconds the similar countrywide implementation of DOTS strategy for TB treatment.

Proportion of New Smear positive, smear negative and EPTB among new cases:

As far as new cases were concerned 44.8%, 22.9% and 32.3% were diagnosed to be new smear positive, smear negative and suffering from Extra pulmonary tuberculosis (EPTB). Our results were quite similar to those reported by WHO, where out of a total of 6.1 million people suffering from TB, 5.7 million (94.3%) were new cases of TB. Among the new cases (diagnosed to be suffering from TB for the first time), 2.5 million (43.8%) were sputum smear-positive, 1.9 million (33.2%) were sputum smear-negative, and 0.8 million (14.0%) were suffering from extra pulmonary TB. India and China together account for 39% of the new and relapse cases of TB in 2012 (23% and 16%, respectively); 60% of TB cases are notified from South-East Asia and Western Pacific Regions where these countries are located [2]. But our results were different from the national figures which state that out of all the new cases, 85-90% suffer from pulmonary TB and 10-15% cases suffer from EPTB[11].

Treatment Outcome/ Cure rates:

The global rate of treatment success for the cohort of 2.6 million new cases of sputum smear-positive pulmonary TB who underwent treatment in the 2011 was 87%[2] which is lower than that found in our study (93.5%) which could be due to the greater magnitude of the study.

The cure rates declined over the three years of study period but still were higher than those reported in TB status report (2007) of Gwalior district (79%) and Madhya Pradesh (79%) [11]. The difference in the cure rates could be due to the fact that Punjab being an affluent state than Madhya Pradesh. People residing in state of Punjab have a better sociodemographic profile and we presume that awareness level and compliancy towards treatment would be more because of higher levels education. Bhat S et al (68%) and Pio et al (50%) also reported quite lower cure rates in their respective studies as compared to our study which could be attributed to the variation in the time of study[12, 13].

Similar success rates among all the categories (95.3%) have been reported by Chadha & Bhagi[14] but Menke et al[15] and Santha et al[16] observed lower cure rates than our study.

During the present study death rate was higher among new smear positive cases (3.6%) as compared to smear negative pulmonary TB (2.0) which were opposite to the results reported by a study conducted in west Bengal where death rate among new sputum positive was 2.6%, among new sputum smear negative pulmonary TB was 5.1%[9].

Another study done in Howarh district reported a failure rate among new sputum positive to be 8.6% and among all cases to be 4.2%, whereas failure rates among new sputum positive was found to be only 1.4% in the present study[9].

Conclusion

Cure rates were higher among EPTB cases whereas default rate was more among patients suffering from pulmonary TB. Therefore higher level of motivation of cases by health and non-health personnel is required as untreated or under treated pulmonary TB cases are responsible for transmission of the disease in the community. Default rates could be decreased by concrete efforts in the form of strict supervision and monitoring. Repeated sensitization of RNTCP is recommended to attain high levels of Treatment success.

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Limitation of the study:

As the study was conducted on secondary data actual picture of the outcome of TB could not be created.

Future scope of the study:

This study could form a basis of state and national level studies to give a true picture of the program.

Author's Contribution:

PP was responsible for designing, data collection and finalization of the manuscript. VG compiled and analysed the data. SD and SC did manuscript writing. GS helped in data collection.

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Conflict of interest:

The authors declares that there is no conflict of interests regarding the publication of this paper.

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