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Research Article

TB Outcome of DOTS Category I TB Cases Started on Re-treatment with Category II Regimen during the Years 2002 to 2015, in a Slum in Delhi

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I N F O

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A B S T R A C T

Objective: This study of TB Cat I cases retreated with Cat II treatment at a DOTS centre, was under taken to gather evidence as to whether TB patients are mostly relapse cases or failure cases and if there is any difference in their final outcome after retreatment.

Methods: The secondary data maintained for a total of 1941 TB patients in the TB register, who were registered & treated from 2002 to the year 2015 at Community Health Department (CHD) DOTS centre of a tertiary care hospital of Delhi was accessed and was entered in excel sheet and Statistical analysis was done using and MedCalc Software bvba [BE]. Out of 1301 total Cat I cases 94 were found who were restarted on Cat II regimen. Out of these 58 (61.7%) were Relapse cases and 36 (38.29%) failure cases.

Result: The mean age was 32.03 with SD+16.33 years and 53.19% were males among 94 Cat I cases enrolled for retreatment. The Cat I Failure cases put on Cat II, showed failure in 12 (33.33%) Vs. failure in relapse cases 10 (17.24%). This low success to treatment (cured and Treatment completed) rate in Failure cases was highly significant ($p<0.0001$).

Conclusion: TB treatment outcome matters a lot. If a TB patient is not cured or does not complete treatment her/his TB could become Drug Resistant. All TB patients should be prevented from becoming failure cases during the course of treatment. If this is done TB morbidity and mortality could be controlled.

Keywords: TB outcome, Re-Treatment Cases, Failure Cases, Relapse Cases

Introduction

In 1993, the WHO had declared TB as a global emergency, and had devised the Directly Observed Treatment-Short course (DOTS), and recommended to follow it by all countries. The concept of "High Burden Country" (HBC)

became familiar and widely used in the context of TB during the period 1998-2015. WHO's post-2015 End Tb Strategy, adopted by the World Health Assembly in 2014, aims to end the global TB epidemic as part of the newly adopted Sustainable Development Goals.[1] The three HBC lists for TB, TB/HIV and MDR-TB, of 30 countries ("20+10") each have been used by WHO from 2016– 2020.[2] There were an estimated 10.0 million new cases of TB disease (also known as active TB) in 2017 globally.

The Government of India revitalized National Tuberculosis Programme (NTP) as Revised National TB Control Programme (RNTCP) and launched DOTS in 1997 and by the end of 2005 the entire country was covered under the programme. During 2006-11, in its second phase RNTCP improved the quality and reach of services, and worked to reach global case detection and cure targets. Despite these achievements, undiagnosed and mistreated cases continued to drive the TB epidemic.[3]

India with its population of 1,34,00,00,000 is a "High TB Burden country". India has Total TB Incidence of 2740000, and HIV Positive TB Incidence of 86000.[4]

The long-term vision of a "TB free India", National Strategic Plan (NSP) for Tuberculosis Control 2012-2017 was documented with the goal of 'universal access to quality TB diagnosis and treatment for all TB patients in the community'. Significant interventions and initiatives such as integration of the programme with the general health services (National Health Mission), Programmatic Management of Drug Resistant TB (PMDT) service expansion, single window service for TB-HIV cases, and national drug resistance surveillance were taken under NSP. The next NSP 2017-2025 is for the control and elimination of TB in India by 2025.

There is a need to understand "who, why and how of a TB patient not cured or did not complete treatment". She/he mostly lands up as a Relapse or a Failure case. Relapse is the commonest cause of administering retreatment regimen with Category II.[5]

This study of TB Cat I cases retreated with Cat II treatment at a DOTS centre, was under taken to throw some light in to the question of "who" these patients are for whom treatment success becomes an illusion ie are they mostly relapse cases or failure cases.

Methods

Study Area: The peripheral unit of a tertiary care hospital is working in a slum and resettlement colony of East Delhi. This colony has a population of 56,502 [Males=28712 and females=27790]. Besides other health and social development programmes it also runs a DOTS clinic since 2002 under Guru Teg Bahadur Chest Clinic.

Study population: All the TB cases put on DOTS treatment between the years 2002 to 2015.

Study Design: A retrospective study.

Study Duration: 15th May 2019-15th September 2019.

Study Sample: Secondary Data maintained in TB register was accessed. A total of 1941 TB patients were registered & treated from 2002 to the year 2015 at Community Health Department (CHD) DOTS centre. The cured & Treatment completed cases were 1700(87.58%). The death rate, default rate and transfer-out rate were well within permissible goals of RNTCP.

Inclusion Criteria: According to secondary data a total of 107 CAT I cases came back for retreatment under CAT II, thus they were included in the study.

Exclusion Criteria: A careful look at 107 cases showed that 13 of these received CAT II treatment repeatedly, as they were not being cured, and there was no DOTS Plus treatment available at that time. So we cleaned the data by excluding these 13 and arrived at the final sample size of 94 (4.84%) (Table 1).

The details of 94 Cat I case including Cat I TB. No., patient's name and c/o, age, sex, religion, address, date of starting Cat I DOTS, pulmonary or extra – pulmonary case, sputum +ve/-ve, and the CAT I outcome etc., were entered on an excel sheet. Next step was entering their case details including Cat II TB No., date of starting Cat II DOTS, type of case - Relapse (R) / Failure (F) /Treatment After Default (TAD) /Other (O) cases, co-morbidities and finally Cat II outcome.

According to the recommendations of the World Health Organization (WHO), patients with recurrent tuberculosis are defined as retreatment cases and are eligible for the standardized category II treatment regimen.[6] In our study definitions of types of cases as New, Relapse, Transferred-in, Treatment after default, Failure, Chronic and Others is taken from Technical and Operational Guidelines of Central TB Division 2005.[7]

Determination of Treatment Outcomes

Cured: If the patient Then the treatment outcome is identified as Was registered as pulmonary smear-positive, completed treatment and had negative smear results on 2 occasions, one of which is at end of treatment.

Treatment completed: Was registered as pulmonary smear-positive, completed treatment with negative smears at the end of the intensive phase but none at end of treatment was registered as pulmonary smear-negative or extra-pulmonary, and completed treatment

Died: Was known to have died from any cause whatsoever while on treatment died.

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Table 1.Total TB Cases Treated at CHD DOTS Centre from 2002 to 2015

Year	Total n	New Spu +ve	Cat I	Cat II	Cat III	Pul	EP	Cured	Rx Comp	Total Cured + Rx Comp	Died	Defaulted	Transferred Out	Failure	Relapse cases came for retreatnent till Dec 2015
2002	33	10	14	7	12	21	12	11	18	11+18 (88%)	1 (3%)	3 (9%)	0	0	
2003	157	39	76	39	42	99	58	39	97	39+97 (87%)	3 (2%)	4 (2.5%)	6 (3.8%)	8 (5%)	4 (2.54%)
2004	118	25	68	29	21	73	45	30	76	30+76 (90%)	4 (3.4%)	1 (0.8%)	3 (2.5%)	4 (3.4%)	8 (6.77%)
2005	140	25	83	44	13	83	57	31	93	31+93 (88.60%)	5 (3.5%)	1 (0.7%)	5 (3.5%)	5 (3.5%)	6 (4.28%)
2006	100	35	68	19	13	71	29	32	52	32+52 (84%)	1 (1%)	2 (2%)	5 (5%)	8 (8%)	3 (3%)
2007	220	58	145	57	18	133	87	71	132	71+132 (92.30%)	3 (1.3%)	7 (3.2%)	5 (2.3%)	2 (0.9%)	8 (3.63%)
2008	150	44	104	32	14	98	52	52	85	52+85 (91%)	7 (4.6%)	1 (1.35%)	1 (1.35%)	4 (2.6%)	11 (7.33%)
2009	146	32	98	40	8	92	54	35	98	35+98 (91%)	3 (2%)	3 (2%)	1 (0.5%)	6 (4%)	8 (5.47%)
2010	136	44	105	29	2	82	54	47	75	47+75 (89.87%)	6 (4.4%)	3 (2.2%)	1 0.79%)	4 (2.9%)	5 (3.67%)
2011	120	48	86	34	0	71	49	37	71	37+71 (90%)	6 (5%)	1 (0.8%)	0 (0%)	5 (4%)	7 (5.83%)
2012	169	77	115	54	0	100	69	54	89	54+89 (84.61%)	4 (2.36%)	7 (4.14%)	1(0.59%)	14 (8.28%)	11 (6.50%)
2013	153	64	109	44	0	87	66	40	91	40+91 (85.62%)	2 (1.30%)	7 (4.57%)	0	13 (8.49%)	7 (4.57%)
2014	145	75	111	34	0	92	53	55	63	55+63 (81.37%)	12 (8.27%)	8 (5.51%)	0	7 (4.82%)	8 (5.51%)
2015	154	53	119	35	0	78	76	35	92	35+91 (81.93%)	8 (5.1%)	15 (9.6%)	1 (0.6%)	4 (2.5%)	8 (5.19%)
Total	1941	629	1301	497	143	1180	761	569	1132	1700	65	63	29	84	94
		32.41	67.03	25.61	7.37	60.79	39.21	29.31	58.32	87.58	3.35	3.25	1.49	4.33	4.84

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Failure: Was registered as pulmonary smear-positive CAT I, and was smear-positive at 5 months or later* Was registered as pulmonary smear-positive CAT II (retreatment), and was smear-positive at five months or later of CAT II treatment Was registered as pulmonary smear-negative or extra-pulmonary on CAT III, but was smear positive any time during treatment*.

Defaulted: Has not taken drugs for more than 2 months consecutively any time after starting treatment

Transferred out: Was transferred to another TU/district and his/her treatment outcome is not available

Note: *Also, re-registered immediately as Category II and started on the re-treatment regimen.

Analysis

Data was entered in MS EXCEL, and Statistical analysis was done using and MedCalc Software bvba [BE].[8] Data was described in the form of percentages and proportions and quantitative variables are described in terms of mean, range and standard deviation. Data was checked for normality before applying appropriate tests of significance. Significance of difference in proportions (qualitative variables) was calculated using chi-square test and for outcomes, using Odds Ratio. Significance of p-value was taken as p<0.05.

Result

A total of 94 out of 1301 Cat I TB cases were found from the department data, who had to be retreated with Cat II regimen at our centre. The mean age for this group was 32.03 (SD ±16.33) years (range 1.5-70 years), for males was 38.09 (SD ±17.8) and for females it was 25.15 (SD ±11.19) with a statically significant difference p<0.0001. Though the number of male patients was more 50 (53.19%) yet we found that among female group there were much younger females that were affected by the disease. This was noticeable in the age group of >10 – 20 years out of total 21 (25.53%) there were 18 (19.14%) females and only 3(3.19%) males and this difference was highly statistically significant with Odds ratio 10.84 [CI 2.9183 to 40.3105] and p=0.0004.

Table 2.Demographic details of Cat I TB patients who underwent treatment with Cat II regimen

S.N.		TB Patients					
1.		**Total sample**	**Males**	**Females**	**Odd's ratio**	**95% CI**	**Significance level 'P'**
		94	50	44			
2.	**Age (Mean, SD)**	32.03 (16.33)	38.09 (17.8)	25.15 (11.19)			0.0001***
3.	**Age (Range)**	1.5 to 70	1.5 to 70	6 to 60			
4.	**Age in years (n, %)**	Total (n, %)	Male	Female			
	>0-10	6 (6.38)	4 (4.25)	2 (2.12)			
	>10-20	21 (22.34)	3 (3.19)	18 (19.14)	10.8462	2.9183 to 40.3105	0.0004***
	>20-30	24 (25.53%)	11 (11.70)	13 (13.82)			
	>30-40	21 (22.34%)	13 (13.82)	8 (8.51)			
	>40-50	6 (6.38%)	6 (6.38)				
	>50-60	10 (10.64%)	7 (7.44)	3(3.19)			
	>60	6 (6.38%)	6 (6.38)				
		94 (100%)	50 (53.19)	44 (46.80)			
5.	**Gender (n, %)**						
	Female	44 (46.81%)					
	Male	50 (53.19%)					
6.	**Religion (n, %)**						
	Hindus	56 (59.57)	35 (37.23)	21 (22.34)			
	Muslims	38 (40.43)	15 (15.96)	23 (24.47)	2.5556	1.0966 to 5.9556	0.0297*
		94 (100%)	50 (53.19%)	44 (46.81%)			

*P<0.5; **p<0.01; ***p<0.001.

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The maximum number of cases were in the age group of >20-30 years - 24(25.53%). There were more Hindus 56(59.57%). Among Muslims there were more females 23(24.47%) than males 15(15.96%) and this difference was also statistically significant Odds ratio 2.55 [CI 1.0966 to 5.9556] and p= 0.0297 (Table 2).

The Pulmonary cases were 75 (79.79%). There were more females with Extra-Pulmonary TB i.e. 13 (13.83%) in comparison to males 6 (6.38%) and this difference was significant with Odds ratio 3.0753 [CI 1.0538 to 8.9744] and p=0.0398. Sputum +ve cases were 70 (74.47%) and more males were sputum +ve 41 (43.62) in comparison to females 29 (30.85%) Odds ratio 2.3563 [CI 0.9081 to 6.1140] and p=0.0781 (Table 3).

The Cat I case that were retreated with Cat II treatment were distributed in two groups – Relapse Group and Failure Group. The overall outcome was good as there were 72 (76.6%) Completed/ Cured, 5 (5.32%) Died, 14 (14.89%) Failure, 2 (2.13%) Transfer-Out and only 1 (1.06) Default case. The failure cases were high (Table 4).

To understand who were the cases most affected and to analyze whether there was any significant difference between outcomes of Cat I Relapse cases put on Cat II and Cat I Failure cases put on Cat II, we re-distributed outcomes in to Successful and Un-successful treatment groups. The Successful group comprised of Cured & Treatment completed cases (1), whereas the Un-successful treatment group comprised of rest of the groups i.e. Died (2), Failure (3), Transfer-out (4) and Default cases (5) as shown in Table 5. The Cat I Failure cases put on Cat II were 12 (33.33%) and showed a highly significant lower success rate (p<0.0001) in comparison to relapse cases 10 (17.24%) (Table 5).

Table 3.Distribution of Cat I TB patients according to site of infection & Sputum positivity

Pulmonary/ extra pulmonary				Odd's ratio	95% CI	Significance level 'P'
	Total (n, %)	Male	Female			
Pulmonary	75 (79.79%)	44 (46.81)	31 (32.98)			
Extra- Pulmonary	19 (20.21%)	6 (6.38)	13 (13.83)	3.0753	1.0538 to 8.9744	0.0398*
	94 (100%)	50 (53.19%)	44 (46.81%)			
Sputum (n, %)						
Sp+	70 (74.47)	41 (43.62)	29 (30.85)	2.3563	0.9081 to 6.1140	0.0781
Sp-	24 (25.53)	9 (9.57)	15 (15.96)			
	94 (100%)	50 (53.19%)	44 (46.81%)			

Table 4.Treatment outcome of Cat I cases put on Cat II regimen

	Total no. of cases		Completed/ Cured (1) (1)		Died (2)		Failure (3)		Transfer out (4)		Default (5)	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Cat I Relapse cases put on Cat II	58	100.00	48	82.76	3	5.17	5	8.62	1	1.72	1	1.72
Cat I Failure cases put on Cat II	36	100.00	24	66.67	2	5.56	9	25.00	1	2.78		
	94	100.00	72	76.60	5	5.32	14	14.89	2	2.13	1	1.06

Table 5.Treatment outcome of Cat I put on Cat II regimen as successful group and unsuccessful group

	n	Successful (1)	Unsuccessful (2+3+4+5)	OR [95%CI]	p-value
Cat I Relapse cases put on Cat II	58	48	10	2.4 0.9082 to 6.3425	0.0774
Cat I Failure cases put on Cat II	36	24	12	0.1 0.0394 to 0.2753	<0.0001***

*P<0.5; **p<0.01; ***p<0.001.

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Discussion

From our data we found a total of 94 Cat I TB cases, had to received retreatment with Cat II regimen at our centre. There were 58 (61.7%) Relapse cases and 36 (38.29%) failure cases. Our rates of Relapse, Failure etc. could be compared to the studies conducted by Chandrasekaran V.[9], Dolma KG[10], Mehra RK[11] and Varshney AM.[12]

In the present study, follow-up of failure and relapse cases of Cat I treatment subsequently treated under Cat II has shown that while relapse sub-group had a successful outcome of 48 (82.76%), the failure sub-group showed a low success 24 (66.67%). Similar comparable results have been reported by, Dhingra VK et al.[13], Chadha SL et al.[14] and Central Tuberculosis Division.[15]

The proportion of patients failing under DOTS has been a matter of concern since the cases who fail not only transmit the infection to others but may also infect others with organisms which may be resistant to the first line drugs.[16] A study from Lima[17] reported 73% MDR strains for Cat I failure cases while Malawi study found proportion of Cat I failure cases showing 0% MDR strains. Santha et al.[18] reported 17% of Cat I failure were having MDR strains.

Patients who failed the Cat I treatment have a high risk of also failing on the Cat II retreatment regimen, and patients who default from a first anti-tuberculosis treatment regimen have a significant risk of also defaulting from the Category II retreatment regimen. Our study found that Cat I Failure cases 12 (33.33%) put on Cat II showed a highly statistically significant lower success rate ($p<0.0001$) in comparison to relapse cases 10 (17.24%). A study found the proportion of patients on Cat II regimen in failure group, showing higher failure rates.[19] Similar results were reported under Revised National Tuberculosis Control Programme with a failure rate of 15.1% for failure group as compared to relapse group 5.2%.

All TB patients should be prevented from becoming failure cases during the course of treatment. If this is done TB morbidity and mortality could be controlled.

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Conflict of Interest: None

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