



TREATMENT OUTCOMES AND THEIR DETERMINANTS AMONGST TUBERCULOSIS PATIENTS AT A DOTS CENTER IN URBAN SLUM

Community Medicine

Dr Chaitali A Borgaonkar Assistant Professor Dept of Community Medicine, H.B.T. Medical College & Dr. R. N. Cooper Hospital, Juhu, Mumbai, Maharashtra. 400 056

Dr Chinmay N Gokhale S.M.O. Dept of Community Medicine, Seth GSMC & KEM Hospital, Parel, Mumbai, Maharashtra. 400 012 (Corresponding Author)

Dr Mridula J Solanki Associate Professor Dept of Community Medicine, Seth GSMC & KEM Hospital, Parel, Mumbai, Maharashtra.

Dr Milind Rasal Assistant Professor Dept of Community Medicine, Seth GSMC & KEM Hospital, Parel, Mumbai, Maharashtra.

Dr Ratnendra R Shinde Professor & Head Dept of Community Medicine, Seth GSMC & KEM Hospital, Parel, Mumbai, Maharashtra.

ABSTRACT

Introduction: Tuberculosis is a major public health problem across the globe and especially in India. The long duration of DOTS makes monitoring of the treatment extremely important. This study was planned in DOTS centre of urban slum area to study treatment outcomes and their determinants amongst TB patients.

Objectives:

1. To assess the treatment outcome of TB patients enrolled in DOTS clinic of UHC.
2. To analyze the determinants of treatment outcome amongst these TB patients.
3. To suggest recommendations to improve performance of the DOTS centre.

Methodology:

This study was a retrospective secondary data based study done in DOTS centre of urban slum area. Data for a 2 years' period was collected for this study from past records. Confidentiality was maintained by using patient numbers instead of names. Significance testing was done using the chi-square tests.

Results & Observations:

A total of 891 patients got included over the period of two years. 829 of these were adult patients, while 62 were from pediatric age group. Extra Pulmonary TB and male gender were significantly associated with treatment success. However, males had significantly higher default as well as death/failure/MDR conversion. Around 25% patients were either transferred out or had an unknown outcome. A large proportion of patients also had an unknown HIV status.

Conclusions: Cat-I treatment, Extra-Pulmonary TB and male patients had better outcomes. The data archiving processes need an up-gradation. Also better collaboration between RNTCP and NACO activities is required. Further studies must be carried to find out socio-demographic determinants.

KEYWORDS:

Treatment Outcomes, Urban Slum

Introduction:

Tuberculosis (TB) is a major public health problem throughout the world. As part of global efforts to control TB, MDG-6 Target 8 is to "Halt and begin to reverse the incidence of TB by 2015." The newer SDGs aim to end the epidemic of tuberculosis BY 2030. The WHO recommended strategy for global tuberculosis control is a short-course clinically administered treatment. The DOTS (Directly Observed Treatment Short course) strategy requires that the patient be treated for eight months which includes a two months intensive phase in which treatment is given under strict supervision by a trained observer, and a six months continuation phase. This is to ensure compliance as well as significantly reduce the rates of relapse and drug resistance. DOTS has been found to be an effective means of administering anti-TB drugs. Monitoring the outcome of treatment is essential in order to evaluate the effectiveness of the intervention. Factors like type and severity of disease due to delay in starting treatment, HIV-status, multidrug-resistance, etc. affect the likelihood of treatment outcome.

Objectives:

1. To assess the treatment outcome of TB patients enrolled in DOTS clinic of Urban health centre.
2. To analyze the determinants of treatment outcome amongst these TB patients.
3. To suggest recommendations to improve performance of the DOTS centre.

Methodology:

It was a Cross sectional retrospective study conducted at Urban Health

Centre of Seth G S Medical College & KEM Hospital, Mumbai located in Malwani, Mumbai. Data of around 891 patients registered at DOTS center between October 2013 and September 2015 in all age groups were included. MDR and XDR were excluded. Data was collected 8 months after the end of above mentioned period to allow for treatment outcomes of all patients from the study period. Confidentiality was maintained by numbering the patients. Data from TB Cards and registers like age, sex, category, type of tuberculosis, sputum examination, etc. were included. Data was entered in Microsoft excel and analysis was done by SPSS software version 21. Outcomes were classified as cured, treatment completed, treatment failure, defaulter, died and transferred out. Standard definitions as per WHO were used to define treatment outcomes.

Results & Observations:

Table 1: Age & Sex Distribution of TB Patients

Age Group	Sex		Total
	Male	Female	
<13	30	32	62 (7%)
13-20	71	151	222 (24.9%)
21-30	108	162	270 (30.3%)
31-40	81	61	142 (15.9%)
41-50	54	33	87 (9.8%)
51-60	32	26	58 (6.5%)
>60	33	17	50 (5.6%)
Total	409	482	891

A total of 891 patients were registered during the two year period. The number of female patients was more than men. 62.5% patients were found to be in the economically productive age group of 20-60 yrs. 5.6% i.e. 50 patients were in geriatric age group whereas 62 patients (7%) were found to be in Paediatric age group.

Table 2: Distribution of patients with various characteristics

Characteristic	Adults	Paediatric	Total
Category			
RNTCP Category-I	610 (68.5%)	59 (6.6%)	669 (75.1%)
RNTCP Category-II	219 (24.6%)	3 (0.3%)	222 (24.9%)
Class			
Pulmonary	547 (61.4%)	38 (4.3%)	585 (65.7%)
Extra Pulmonary	282 (31.6%)	24 (2.7%)	306 (34.3%)
Outcome			
Cured	154 (17.3%)	2 (0.2%)	156 (17.5%)
Treatment Completed	327 (36.7%)	42 (4.7%)	369 (41.4%)
Default	64 (7.2%)	3 (0.3%)	67 (7.5%)
Died	21 (2.4%)	2 (0.2%)	23 (2.6%)
MDR	43 (4.8%)	1 (0.1%)	44 (4.9%)
Unknown	199 (22.3%)	12 (1.3%)	211 (23.7%)
Transferred Out	15 (1.7%)	0	15 (1.7%)
Failed	6 (0.7%)	0	6 (0.7%)
HIV Status			
Positive	21 (2.4%)	2 (0.2%)	23 (2.6%)
Negative	500 (56.1%)	21 (2.4%)	521 (58.5%)
Unknown	308 (34.6%)	39 (4.4%)	347 (38.9%)
Total			
Total	829 (93%)	62 (7%)	891 (100%)

The study included 829 (93%) adults ranging from age 13- 90 years. Another 62 (7%) were in paediatric age group. In both the age groups most patients (75.1%) belonged to Category 1. Pulmonary Tuberculosis (65.7%) was more common than extra pulmonary. 2.6% patients were HIV positive while 58.5 % had HIV negative status.

Treatment completed was the most common (41.4%) outcome followed by Cured (17.5%). Treatment success was thus 58.9%. Only 6 (0.7%) failed and 15 (1.7%) were transferred out. Surprisingly outcomes of 23.7% patients were unknown. Mortality rate was 2.6%. 67 patients i.e. 7.5% had defaulted, however the reason for default were not known.

Treatment success was recorded more in CAT 1 and paediatric age group although this was not statistically significant. Treatment success was also better in Extra-pulmonary TB.

Table 3: Distribution of Subjects as per RNTCP Category

Characteristic	RNTCP Category		Total
	I	II	
Male	290 (70.9%)	119 (29.1%)	409
Female	379 (78.6%)	103 (21.4%)	482
$X^2 = 7.06 \quad p = 0.0078$			
Pulmonary	414 (72.5%)	157 (27.5%)	571
Extra Pulmonary	255 (79.7%)	65 (20.3%)	320
$X^2 = 5.66 \quad p = 0.0174$			

The patients in categories I and II were compared against gender and class of Tuberculosis. It can be seen that more females (78.6%) were under Cat-I treatment whereas more males were receiving Cat-II. These findings were statistically significant.

When compared by class of Tuberculosis it can be seen that 79.7% of patients with Extra-Pulmonary TB were on Cat-I treatment as oppose to 72.5% of Pulmonary TB on Cat-I. These differences were statistically significant using the chi-square test. This also shows that

more Pulmonary TB cases were on Cat-II. This may be due to higher incidence of failure or relapse in Pulmonary TB as compared to Extra-Pulmonary TB.

Table 4: Distribution of Subjects as per Treatment Outcomes

Characteristics	Outcome				Total
	Success*	Default	D/MDR/F**	TO/U**	
Male	242 (59.2%)	45 (11%)	43 (10.5%)	79 (19.3%)	409
Female	283 (58.7%)	22 (4.6%)	30 (6.2%)	147 (30.5%)	482
$X^2 = 28.08 \quad p < 0.00001$					
HIV+	9 (39.1%)	5 (21.7%)	5 (21.7%)	4 (17.5%)	23
HIV-	256 (49.1%)	26 (5%)	28 (5.4%)	211 (40.5%)	521
HIV U	260 (74.9%)	36 (10.4%)	40 (11.5%)	11 (3.2%)	347
$X^2 = 169.4 \quad p < 0.00001$					
CAT I	413 (61.7%)	42 (6.3%)	47 (7%)	167 (25%)	669
CAT II	112 (50.5%)	25 (11.3%)	26 (11.7%)	59 (26.5%)	222
$X^2 = 13.75 \quad p = 0.003273$					
Pulmonary	314 (55%)	58 (10.2%)	66 (11.6%)	133 (23.2%)	571
Extra Pulmonary	211 (65.9%)	9 (2.8%)	7 (2.2%)	93 (29.1%)	320
$X^2 = 43.56 \quad p < 0.0000001$					
Total	525 (59.1%)	67 (7.5%)	73 (8.2%)	226 (25.4%)	891

- * Success Treatment outcome includes Cured and Treatment Completed.
- ** For statistical purposes Died, MDR and Failure have been clubbed. Similarly, Transferred out and Unknown outcomes have been clubbed.

The Treatment outcomes have been compared against various patient characteristics in Table 4. It can be seen that males had a slightly better treatment success than females. However, the default rate amongst males (11%) was significantly higher in males as compared to 4.6% in females. Also the rate of death/MDR/failure is also higher in male gender.

There was a treatment success rate of 39.1% among HIV positive individuals. However, a large proportion of patients are found in HIV status unknown group.

Treatment success in Cat-I patients (61.7%) was significantly higher than 50.5% in Cat-II patients. Also Cat-II patients have a higher rate of Defaulting and also a higher rate of death/failure/conversion to MDR. Surprisingly, around 25% patients of both Cat-I and Cat-II were either transferred out or their treatment outcomes were unknown.

In the comparison between Pulmonary and Extra-pulmonary forms of TB, it can be seen that not only the treatment success rates are higher in Extra-Pulmonary TB but also the rates of default or death/failure/MDR are lower. On application of chi-square test these findings are found to be statistically significant.

Discussion:

A total of 891 patients were registered during the two year period. The number of female patients was more than men. Similar findings were seen in study by Belete G. et al conducted in Ethiopia.⁽¹⁾ Among 417 study participants 108 (52.3%) were females and 199 (47.7%) were males in study by Mengistu E et al.⁽⁶⁾ 62.5% patients were found to be in the economically productive age group of 20-60 yrs. Whereas Belete G. et al⁽¹⁾ in Ethiopia found 78% patients in productive age groups. 5.6% i.e. 50 patients were in geriatric age group whereas 62 patients (7%) were found to be in Paediatric age group. Children <14 years accounted for 14.6% of the study participants in study by Mengistu E. et al.⁽⁶⁾

Pulmonary Tuberculosis (65.7%) was more common than extra pulmonary. Similar findings were seen in study by Chennaveerappa PK et al⁽⁵⁾ where 65% patients had pulmonary tuberculosis. In this study 2.6% patients were HIV positive while 58.5 % had HIV negative status. In study by Oluwole B et al⁽²⁾ 20.0% had HIV/AIDS co-infection. Hence, the HIV positive proportion was much lower than a

previous study. However, a large number of patients had a n unknown HIV status indicating the lack of collaboration between RNTCP and NACO activities.

Treatment completed was the most common (41.4%) outcome followed by Cured (17.5%). Treatment success was thus 58.9%. This was much less than National results of 2014 where 83% were cured and 4% treatment completed. In 2014, 4% died, 2% failure and 5% defaulted. ⁽⁸⁾ Only 6 (0.7%) failed and 15 (1.7%) were transferred out. Study by Belete G. et al conducted in Ethiopia ⁽¹⁾ found 18% cured, 64.6% completed treatment, 3.7% died, 0.4% were treatment failure, 5.1 defaulted, and 5.4 transferred out. Total success rate was 83.4% in study by Chennaveerappa PK. ⁽³⁾ Hence, the treatment success rates were much lower in this study as compared to previous studies.

Treatment success was recorded more in paediatric age group although this was not statistically significant. Treatment success was also better in Extra- pulmonary TB. Similar findings were seen in study by Bong N S et al in Cameroon. ⁽⁷⁾ However, poorer outcome was recorded in patients with extra-pulmonary TB than among patients with pulmonary TB in study by Oluwole B et al. ⁽²⁾

In this study it can be seen that males had a slightly better treatment success rate than females whereas in study by Bong N S et al in Cameroon, female patients registered higher treatment success rate. ⁽⁷⁾ However, the default rate amongst males (11%) was significantly higher as compared to 4.6% in females. Also the rate of death/MDR/failure is also higher in male gender. This was similar to findings of Qing-Song Bao et al ⁽⁹⁾ where un-successful outcomes were more common among males than among females. Finally it can be seen that 25.4% were either transferred out or had an Unknown outcome. This sums up to the fact that outcome of 1 out of 4 patients is not available at this DOTS centre. However many of these outcomes would have been updated after this data was collected and analysed still missing out on outcome of 226 out of 891 patients suggests that a more stringent data maintaining process needs to be followed. However, since the study area was an urban slum with high amount of in-migration as well as out-migration, the number of patients transferred in and out is expected to be higher than other DOTS centres.

Conclusion:

The treatment success rate of DOTS centre in the urban slum area was very low. Treatment success was better in Extra- pulmonary TB patients. Males had a slightly better treatment success than females. However, Outcomes of large number of patients were unknown. Also a large number of TB patients had an unknown HIV status. This study points towards a need of upgrading the data archiving processes followed under RNTCP DOTS.

Recommendations:

1. There is a need for upgrading the data archiving process to make treatment outcomes of almost all patients registered at any DOTS centre available for analysis. Use of Internet and e-portals can aid in better data management.
2. Stronger and Smoother collaboration between RNTCP and NACO activities will help in screening all TB patients for Retrovirus status.
3. In-depth studies should be conducted to determine the reasons for default which will help organise managerial tools to increase compliance.
4. Further studies must be conducted on a regular basis especially in slum settings to monitor the performance of TB control activities.

Limitations:

As this study was conducted using secondary data, many socio-demographic determinants influencing treatment outcomes could not be explored. Primary Data based studies must be carried to find out the same.

Conflicts of Interest: None

Funding: None

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