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## TREATMENT OUTCOME OF TUBERCULOSIS PATIENTS ON DOTS THERAPY FOR CATEGORY 1 AND 2 AT DISTRICT TUBERCULOSIS CENTRE

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**ABSTRACT: Background:** India is highest tuberculosis (TB) burden country accounting for approximately 20% of global TB burden. To tackle this problem, Revised National Tuberculosis Control Programme (RNTCP) based on the DOTS (Directly Observed Treatment Short course) strategy has been made available in the entire country by March 2006. Present study describes the achievements under RNTCP in terms of treatment outcomes, smear conversion rate and evaluation of risk factors for unsuccessful treatment outcome at district tuberculosis centre.


**Objectives:** Treatment outcome of tuberculosis (TB) patients on DOTS (category 1 & 2) and evaluation of predictors for unsuccessful outcome. **Methodology:** A record-based retrospective study; analysis of cases registered for treatment for Cat - 1 & 2 at district tuberculosis centre during 2013 & 2014 was done. Data regarding demographic profile, TB type & categories, investigation, treatment outcome and co morbidity were recorded. Data were analyzed and appropriate statistical test was done using Epi info 7, CDC. **Result:** Out of 1340 registered cases, 1081 (80.67%) were of cat1 and 259 (19.33%) were of cat-2 TB. Majority patients (66.19%) were in 15-44 years of age group. Ratio of Male to female was 2.45: 1 while pulmonary TB to extrapulmonary TB was 3.75:1. Cure rate of whole cohort was 90.29%, while defaulter rate, death rate, treatment failure and transferred out cases were 2.31%, 4.10 %, 1.49% and 1.79% respectively. Unsuccessful outcome was significantly associated with age  $\geq 65$  years and those who lost weight during treatment.

**Conclusion:** Target norm set by RNTCP was achieved at district TB centre.

**INTRODUCTION:** Although significant progress has been made in global Tuberculosis (TB) control over the past decade, it ranks the second leading cause of death from all infectious disease worldwide<sup>1, 2</sup>. India is one of the highest TB burden country accounting for approximately 1/5th of global TB burden. To tackle this problem, Revised National Tuberculosis Control Programme (RNTCP) based on the DOTS (Directly Observed Treatment-Short course) strategy has been made available in the entire country by March 2006.

This is to ensure drug compliance and increase cure rates of patients with TB. Cure rates and a success rate of 88% among new smear positive cases were reported in 2011 in India.<sup>3, 4, 5</sup> Treatment outcome criteria by WHO/IUATLD (International Union Against Tuberculosis and Lung disease) includes cure, treatment completion, treatment failure, death, default, and transfer out,<sup>6</sup> while slightly modified version of WHO/IUATLD includes success rate and unsuccessful rate<sup>7</sup>. Present study describes treatment outcomes, conversion rates and evaluation of risk factors which have impact on treatment outcome.

**MATERIAL AND METHOD:** It was a record-based retrospective study; analysis of the cases registered for tuberculosis treatment for category 1 & 2 in the district tuberculosis centre (DTC) during 2013 & 2014 was done.

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This data was obtained from the TB treatment card and register maintained at the TB centre. Ethical clearance and permission from the District Tuberculosis Officer was obtained. The information collected included age and gender of the patient, category of treatment (cat 1 & 2), disease type (pulmonary/extrapulmonary), date of initiation of treatment, body weight, sputum conversion at the end of intensive phase, outcome of treatment and adverse drug reaction and co morbid situation (HIV and diabetic status). Outcome of treatment for a TB patient was evaluated as per WHO and as WHO new modified criteria. Sputum conversion rate was also evaluated. Various risk factors like age, weight,

gender, TB type (P/EP), category (1&2), co morbidity association with unsuccessful treatment outcome was evaluated. Few patients registered under RNTCP but those were on non-DOTS treatment, multidrug resistant (MDR) and Extensive drug resistant (XDR) cases were excluded from the study. Data were recorded in Microsoft office excel 2007 and appropriate statistical test were done using Epi info 7, CDC.

**RESULT:** During 2013-14, total 1340 cases were registered at DTC which included 1081 (80.67%) of category 1 and 259 (19.33%) of category 2 of tuberculosis patients.

**TABLE 1: SOCIO-DEMOGRAPHIC PROFILE OF TUBERCULOSIS CATEGORIES.**

Sociodemographic factors	No of cases of Cat-1, n=1081(%)	No of cases of Cat 2, n=259(%)	Total no. n=1340 (%)
<b>Age</b>			
<15	67(6.19)	8(3.08)	75(5.59)
15-44	721(66.69)	166(64.09)	887(66.19)
45-64	212(19.61)	62(23.93)	274(20.44)
≥65 and above	83(7.67)	21(8.10)	104(7.76)
<b>Gender</b>			
Male*	758(70.12)	193(74.51)	952(71.04)
Female	324(29.97)	64(24.71)	388(28.95)
<b>Tb variety</b>			
Pulmonary†	842(77.89)†	216(83.39)†	1058(78.95)
Extrapulmonary	238(21.99)	48(18.53)	282(21.04)
<b>Co morbidity</b>			
Diabetes	115(10.63)	18(6.94)	133(9.92)
HIV§	25(2.31)	13(5.01)§	38(2.83)
Diabetes and HIV	3(0.027)	0	3(0.22)
<b>Initial Bodyweight</b>			
<45kg	788(72.89)	174(67.18)	962(71.79)
>45 kg	494 (45.69)	83(32.04)	577(43.05)

\*Male gender involvement in both category was significantly higher than female ( $\chi^2= 2.539$ ,  $p=0.027$ )

† Pulmonary tuberculosis was more than extrapulmonary in both categories ( $\chi^2=4.961$ ,  $p=0.027$ )

§ HIV patients significantly associated with cat 2( $\chi^2=5.772$ ,  $p=0.056$ )

Majority patients (66.19%) were in 15-44years of age group followed by late middle age group (45-60 years, 20.44%) and geriatric ( $\geq 65$  years, 0.07%) and up to adolescent (upto 15, 0.05%) in both categories in this study. Mean age in both categories of TB patients was 35.58years. 71.04% were male patients while 28.95% were females. Pulmonary tuberculosis (P) cases registered around two third of total (78.95%) while 21.04 % cases of extrapulmonary tuberculosis (EP). Ratio between P and EP cases was 3.75:1 in the present study. Mean age of male patients affected in P, EP cases

was 37.83 and 32.76years respectively. While mean age of females in P, EP cases was 33.64years and 28.9years. Even though majority patients were observed in young adult and middle age group, initial body weight was lower (below 45kg) in present study, which was statically significant. Co infection with HIV was found in only 2.83% of the total cases registered at DTC, while diabetic cases were 9.92% while both diabetes and HIV both found only in 3 patients. Cat 2 was significantly associated with HIV co morbidity.

Sputum conversion rate: Out of 1058 pulmonary cases, 88.14% were sputum smear positive. Smear conversion rate of 95% was found among smear positive pulmonary cases.

**TABLE 2: TREATMENT OUTCOME BY WHO/IUATLD AMONG CAT 1 & CAT 2 (N=1340)**

TB category	Cure	Defaulter	Death	Treatment failure	Transferred out and status not known
Cat 1 (n=1081)	991(91.67)	15(1.38))	40(3.70)	14(1.29)	21(1.94)
Cat 2 (n=259)	219(84.55)	16(6.17)*	15(5.79)*	6(2.31*)	3(1.15)*
Total (n= 1340)	1210 (90.29)	31(2.31)	55(4.10)	20(1.49)	24(1.79)

\*( $\chi^2=23.966$ , df= 4, p=0.000)

Cure rate of cohort was 90.29% while defaulter rate, death rate, treatment failure and transferred out cases were 2.31%, 4.10 %, 1.49% and 1.79% respectively. Cure rate was higher in cat1 patients while defaulter rate, death rate and treatment failure rate was higher among cat 2 which was stastically significant.

**TABLE 3: TREATMENT OUTCOME BY WHO/IUATLD MODIFIED CRITERIA (n=1340)**

	Treatment Outcome		Total (n=1340)
	Successful (%)	Unsuccessful (%)	
<b>Age (years)</b>			
<15	72(94.74)	4(5.26)	76 (5.6)
15-44	819(92.33)	68(7.66)	887(66.19)
45-64	239(87.55)	34(12.45)	274(20.44)
≥65 and above	87(83.65)	17(16.34)*	104(7.76)
<b>Gender</b>			
Male	859(90.23)	93(9.76)	952(71.04)
Female	358(92.27)	30(7.73)	388(28.95)
<b>Category of tuberculosis</b>			
Category -1	991(91.67)	90(8.32)	1081(80.67)
Category-2	219(84.55)	40(15.44)	259(19.32)
<b>Tuberculosis type</b>			
Pulmonary	956(90.35)	101(9.54)	1058(78.95)
Extrapulmonary	253(89.71)	29(10.28)	282(21.04)
<b>Co-morbidity</b>			
Diabetes	121(90.98)	12(9.02)	133(9.99)
HIV	33(86.84)	5(13.15)	38(2.83)
Diabetes and HIV	3(100)	0	3(0.2)
<b>Weight status (after treatment)</b>			
Weight improved	977(95.88)	42(4.12)	1019(76.04)
Stable	23(76.67)	7(23.33)	30(2.23)
Decreases weight†	117(75.48)	38(24.51)	155(11.56)
Stats not known	100(73.53)	36(26.47)	136(10.14)

\*Unsuccessful outcome significantly associated with age ≥65 years (( $\chi^2=13.878$ , df= 3, P=0.002)

†decreased weight after treatment ( $\chi^2=137.416$ , df=3, P=0.000).

Success rate was higher among age group of 15-44years, female gender, cat1 and pulmonary cases. Improvement in weight was stastically significant associated with cure rate. Geriatric age group (≥65 years) and those who had lost weight throughout treatment was associated with unsuccessful outcome in present study which was stastically significant.

**DISCUSSION:** Under the 12<sup>th</sup> Five Year Plan of Government of India as National Strategic Plan for 2012-17, target set for detection of new cases is at least 90% of total estimated cases and cure rate of

90% with new cases and 85% in retreated cases<sup>8</sup>. In present study, majority of patients (66.19%) were observed in the age group of 15-44 yrs of age group. Mean age in both P and EP TB cases was 35year. This is the most socioeconomically productive segment of the population unlike developed countries where TB affects mainly the elderly<sup>9</sup>. Young adults because of their age factor and socio-economic dependence of family; they involve themselves in earning and get exposed to other cases in community<sup>10</sup>.

Other studies done by Kadeangadi DM et al, Ahmad SR et al, Akinola A et al. also supports the same productive age affected by tuberculosis<sup>11, 12, 13</sup>. Males were more affected than females (M: F ratio was 3.75:1) in present study. Other studies also had the similar finding in various states of India as well other countries<sup>14, 15, 16, 17, 18</sup>.

Observable differences in morbidity by sex can be attributable to differences in the risk of becoming and being infected, differences in morbidity risk given infection, and finally the gender issue of differences in accessibility to diagnosis.

The ratio between P/EP cases was 3.75:1 which is less as compared to the expected RNTCP norm of 10:1<sup>19</sup>. This data differs from the national figure which states that 85-90% of cases are pulmonary tuberculosis and 10- 15% of cases are extrapulmonary tuberculosis<sup>20</sup>. Pulmonary TB cases (78.95%) were more reported than extrapulmonary cases (21.04 %) of TB in current study. Various studies done in Karnataka, Uttarpradesh, West Bangal, Pondicherry and Israel also reported more pulmonary cases than extrapulmonary cases of tuberculosis<sup>4, 11, 21, 22, 23</sup>. Among the sputum positive pulmonary cases, cure rate and sputum conversion rates were linearly associated with initial smear grading.<sup>24</sup> 95% sputum smear conversion rate and good cure rate (91.91%) were achieved in present study which were higher than the target set by RNTCP.

This result also coincides with other study results<sup>25</sup>. Outcome was not stastically significant in both P and EP variety of TB. In the extrapulmonary cases, lymph nodes were the most commonly involved followed by pleura, abdomen, meninges and joint. Lymph nodes was also more affected in EP TB in study done by Chemtob D and V. K. Arora.<sup>15</sup>. Cervical lymph nodes and axillary lymph nodes were the most commonly involved lymphnodes which were commonly found in other studies also<sup>23</sup>.

In present study 84% of pulmonary cases show improvement in weight gain at end of therapy and cure rate among them was 95% which was stastically significant. Unsuccessful outcome strongly associated with those who had lost weight throughout treatment. People with active TB are

often malnourished and suffer from micronutrient deficiencies as well as weight loss and decreased appetite<sup>26</sup>. Apart from clinical evaluation and sputum smear conversion, weight is also considered an important parameter to be measured in pulmonary cases. TB is a wasting disease and it is claimed that body weight is a predictor of response to treatment and it is expected that the patients who lost weight during the course of disease, will gain weight during successful treatment. Possible association between weight changes during treatment and treatment outcome has been investigated in some studies.<sup>27</sup>

Co morbidity of TB -HIV and TB - diabetic cases was 2.83% and 9.92% of the total registered cases at DTC. Cure rate was in TB-HIV was 86.84%. While in TB-diabetic cases were 90.93%. The association of TB with co morbidity and treatment outcome was not conclusive in our study as data regards to co morbidity of many patients were deficient from the records.

Success/Cure rate is an important parameter for assessing the effect of for TB outcome. It varies from place to place throughout the world. In current study, success rate of DOTS was 90.26% [in cat -1(91.67%), cat -2 (84.55%)], which was higher than the best performing districts of RNTCP in India (80-85%) and other studies conducted in Hassan district of Karnataka (83.4%) and Nellore district in Andhra Pradesh (88.5%)<sup>27</sup>. The WHO's global target for infectious TB cases is a cure rate of 85%, and the WHO/IUATLD classification stipulates not more than 10% of "probably unsatisfactory outcome" cases<sup>28</sup>.

Success rate was higher among age group (15-44years), female gender, category 1 and pulmonary cases. Ahmad and Velhal and da Silva Garrido *et al.* reported age to be a significant factor associated with treatment outcome<sup>29, 30</sup>. Ditah *et al.* also found older age to be a significant risk factor for unsuccessful outcome<sup>15</sup>. Decline of immunity with age might be the reason. Success rate was found higher among females while failure rate was higher among male. Study done by Ahmad and Velhal and Mukherjee *et al.* also show that the cure rate was significantly higher in females compared to males<sup>14, 29</sup>.

Other studies also revealed that males are at an increased risk of a poor treatment outcome compared to females<sup>33</sup>. This study has supported that the cure was significantly associated with improvement of patient's body weight. Unsuccessful outcome significantly associated with geriatric age group, cat 2 with HIV patients as well those who had reduction of weight while on treatment in our study.

Apart from various factors associated with tuberculosis and its outcome, role of TB centre plays a crucial role for ensuring the completion of therapy. The majority of unsuccessful outcomes were due to a failure of the programme to ensure treatment, rather than a failure of treatment to cure the patients. Tuberculosis outcome surveillance is important as it allows the measurement and comparison of the performance of tuberculosis services locally, regionally, nationally and internationally. The collection of information on outcomes depends heavily on the collaboration of local tuberculosis departments. It allows local tuberculosis departments to list all cases where the tuberculosis service failed, and perform a review of such cases<sup>16</sup>. This district TB centre got excellence for highest cure rate in year 2014.

Private sector predominates in health care and TB treatment. In order to ensure proper TB diagnosis and case management, reduce TB transmission and address the problems of emergence of spread of Drug Resistant-TB, it is essential to have complete information of all TB cases. Therefore, Govt. of India declared Tuberculosis a notifiable disease on 7th May 2012. In this DTC notification of cases by private sector was raised from 534 cases to 1438 cases from year 2013 to 2015 which show the awareness of private health professional and there by more number of TB cases coverage by RNTCP ensuring complete treatment.

**CONCLUSION:** The expected treatment outcome norm set by RNTCP (cure rate > 90%, failure rate <4%, death rate <4%, default rate <5%, smear conversion rate >90%) were achieved in the present study. Geriatric age group ( $\geq 60$  years) and those who had lost weight during treatment was predictor for unsuccessful outcome. There is a need for the collection of information on co morbid states, addiction details, and adverse drug reactions in

order to give a better understanding of tuberculosis management. Tuberculosis management should integrate risk assessment for unsuccessful treatment outcome.

**STUDY LIMITATION:** As study is retrospective, outcome evaluation was done on basis of information obtained from the card which was lacking in many aspects like adverse drug reaction, progress of disease, addictions details, and hospitalization. These factors might have impact on outcome. Any bias introduced by lack of availability of data, however, underestimates the association between potential risk factors and treatment outcomes; availability of missing information would have strengthened the association between risk factors and treatment outcomes.

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