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ORIGINAL ARTICLE

TREATMENT OUTCOMES IN PATIENTS TREATED UNDER RNTCP IN KARAD TUBERCULOSIS UNIT

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ABSTRACT: BACKGROUND: The Revised National Tuberculosis Control Programme (RNTCP), India. **OBJECTIVE:** To study the treatment outcomes in patients treated under RNTCP &causes of defaulted, death, failure among them. **MATERIAL & METHODS:** This study was conducted in Karad Tuberculosis Unit (TU), Satara District, Maharashtra. Under Karad Tuberculosis Unit there were nine PHCs, Sub District Hospital and Krishna Hospital, six Designated Microscopy Centre's (DMC), three Integrated Counseling and Testing Centre's (ICTC) – KH, SDH and Undale. All patients registered during January2008 to June 2009 i.e.806 were the study subjects. Before commencement of study permission of District Tuberculosis Officer (DTO) was taken. **STUDY TYPE:** Longitudinal (Prospective) Study. **STUDY PLAN:** Patients were interviewed using pre-tested semi structured questionnaires at their residence at the start of treatment, after completion of intensive phase and cohort was further followed up for approximately six months. **RESULTS & OBSERVATIONS:** Out of 233 new sputum smear positive (NSP) patients, 214 had their sputum smear negative at the end of Intensive phase (IP); hence sputum conversion rate was 91.84% in present study. We found that233newsputum smear positive cases out of which 187 were cured. Thus the cure rate was 80.2%.Out of which 506 smear negative and extra pulmonary patients 462 completed treatment hence treatment completion rate was 91.30%. Out of 233 new smear sputum positive cases, 23 died thus death rate was 9.8%, 5 patients were treatment failure thus the failure rate was 2.1 %. 12 patients defaulted the treatment thus defaulted rate was5.15%.Due to tuberculosis 22 (2.7%) patients died, 27 (3.3%) due to HIV, 17 (2.1%) defaulted due to migration, 5 (0.6%) defaulted due to addiction of alcohol, 3 (0.4%) defaulted due to not relief from symptoms, 1 (0.1%) defaulted due to adverse reaction.16 (2%) failed in due to initial heavy bacillary load. **CONCLUSION:** It is observed that our regimens produced decline in failure rate, default rate was near expected, death rate was little more. As cure rate was very close to RNTCP objectives, reason might be good case holding in the study. The present study revealed that deaths due to pulmonary tuberculosis even after treatment& HIV renders individuals more susceptible to death as in these study 27 deaths are due to HIV. Some people migrate to their native place or for their work and become defaulted. Default was attributed to migration to their native places in this study. Majority of cases of failure might be due to initial heavy bacillary load.

KEYWORDS: RNTCP, DTO, DMC, ICTC, IP, TU.

INTRODUCTION: Tuberculosis is one of the man's oldest foes. One of triumphs of modern medicine has been the development of vaccination and medication capable of combating this ancient disease. The disease is more common in those who are socially deprived. For Tuberculosis paradox is that although it is easy to diagnose and treat, it is an increasing global scourge and the leading cause of death amongst chronic infectiousdiseases.[1] If left untreated each person with active TB will infect on

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an average between 10-15 people every year. The circumstances have changed due to multi drug resistance of organisms and emergence other/AIDS. HIV and AIDS have aggravated the tuberculosis burden. The stigma attached to TB adds to burden of disease for both men and women even more so if they are marriageable age. Men have to deal with the stigma at their workplace and in the community and women are ostracized in household and community.[2] Considering above scenario the present research was undertaken alike various research done in this field.

AIMS AND OBJECTIVE:

1) To study the outcomes of DOTS treatment among patients under RNTCP.
2) To find out causes/factors associated with default, failure death.

MATERIAL AND METHODS:

1) **STUDY COHORT:** All patients registered in Karad Tuberculosis Unit selected from January 2008 to June 2009, from the cohort for two phases of community based cohort analysis. i.e. 806 patients formed the study cohort. Hence no sampling procedure was used. Under Karad Tuberculosis Unit there are nine PHCs, Sub District Hospital and Krishna Hospital, six Designated Microscopy Centres (DMC), three Integrated Counselling and Testing Centres (ICTC) – KH, SDH and Undale. Before commencement of study permission of District Tuberculosis Officer (DTO) was taken.
2) **Study Period:** January 2008 to June 2009.Data collection from October 2008 to April 2010.Analysis done May 2010.
3) **Type of Study:** Longitudinal (Prospective) Study.
4) **Study Plan:** Phase I.

DATA COLLECTION: Patients were interviewed using pre-tested semi structured questionnaires at their residence after treatment initiation, after completion of intensive phase and at the end of continuation phase. Initial interviews and review of available records elicited information on history of previous anti-TB treatment if any and details thereof.

PHASE II: The cohort was further followed up for approximately six months. For patients reported dead, cause of death was obtained from close relatives through questionnaires based on interviews and scrutiny of available records including death certificate.

STATISTICAL METHODS: (DATA ANALYSIS): Data was summarized in number and in percentage. Appropriate techniques used.

OBSERVATIONS:

Age Groups	Gender		
	Male	Female	Total
Below 15 yrs	18 3.8%	13 3.9%	31 3.8%
15-29 yrs	105 22.1%	106 32.0%	211 26.2%

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30-44yrs	169 35.6%	121 36.6%	290 36.0%
45-59yrs	110 23.2%	54 16.3%	164 20.3%
60yrs & above	73 15.4%	37 11.2%	110 13.6%
Total	**475 100.0%**	**331 100.0%**	**806 100.0%**

Table 1: Age and gender wise distribution of patients

$\chi 2 = 14.392$, df. = 4, p = 0.006

Category	Sputum Smear Negative	Sputum Smear Positive	Extra-Pulmonary	Total
CAT-I	209 38.08%	233 42.44%	107 19.5%	549 68.1%
CAT -II	47 36.71%	67 52.3%	0 0.0%	114 14.1%
CAT-III	64 48.83%	0 0.0%	79 55.2%	143 17.7%
Total	**320 39.7%**	**300 37.22%**	**186 23.07%**	**806 100%**

Table 2: Category wise distribution of patient

DOTS Category	Type of Patient	Cured		Treatment Completed		Defaulted		Died		Failure		Transferred out		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%
CAT –I	New sputum + ve, PTB	187	80.8	4	1.7	12	2.5	23	9.9	5	2.1	2	0.8	233	100
	New sputum - ve, Seriously ill* PTB	18	8.6	155	74.1	10	4.8	21	10	-	-	5	2.4	209	100
	New Extra-PTB, Seriously ill*	4	3.7	88	82.2	2	1.9	10	9.3	1	0.9	2	1.9	107	100
	Total	209	38	247	45	24	4.4	54	9.8	6	1.1	9	1.6	549	100
CAT - II	Sputum smear	21	31.3	23	34.3	3	4.5	8	11.9	11	16.4	1	1.5	67	100

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	+ve(Relapse + Failure +Treatment after default)														
	Extra-pulmonary TB	-	-	11	78.6	1	7.1	1	7.1	-	-	1	7.1	14	100
	Others**	4	8.5	36	76.6	1	2.1	5	10.6	-	-	1	2.2	47	100
	Total	25	19.5	70	54.7	5	3.9	14	10.9	11	8.6	3	2.3	128	100
CAT - III	New sputum smear – ve not seriously ill	3	4.7	55	85.9	1	1.5	2	3.1	3	4.7	-	-	64	100
	New Extra-pulmonary not seriously ill	2	3.1	59	90.8	1	1.5	1	1.5	-	-	2	3.1	65	100
	Total	**5**	**3.9**	**114**	**88.4**	**2**	**1.6**	**3**	**2.3**	**3**	**2.3**	**2**	**1.6**	**129**	**100**
Total		**239**	**29.7**	**431**	**53.5**	**31**	**3.8**	**71**	**8.8**	**20**	**2.5**	**14**	**1.7**	**806**	**100**

Table 3: Distribution of tuberculosis patients according to their Treatment. Outcomes (n=806)

* Seriously ill includes pulmonary or extra-pulmonary who were HIV +ve.

** Sputum smear –ve or who had extra-pulmonary disease can have relapse or failure.

$\chi 2 = 84.947$, df = 10, $p < 0.001$

Out of 678 new cases of tuberculosis, 233 were new sputum smear positive. Out of 233 new sputum smear positive patients, 214had their sputum smear negative at the end of Intensive phase; hence sputum conversion rate was 91.84% in present study. We found that233 new sputum smear positive cases out of which 187 were cured. Thus the cure rate was 80.2%.

Out of which 506 smear negative and extra pulmonary patients462 completed treatment hence treatment completion rate was91.30%.

Out of 233 new smear sputum positive cases, 23 died thus death rate was 9.8%, 5 patients were treatment failure thus the failure rate was 2.1 %.

12 patients defaulted the treatment thus defaulted rate was5.15% which is near about the expected RNTCP default rate. There were 9 patients among new sputum positive cases who we retransferred out. Thus the transfer rate was 1.67%.

Causes	*	Died	Defaulted	Failure	Total
Abdomen Koch's + HIV		2 0.2%	0 0.0%	0 0.0%	2 0.2%
Alcoholic liver cirrhosis		8 1%	5 0.6%	0 0.0%	13 1.6%
Asthmatic bronchitis		1 0.1%	0 0.0%	0 0.0%	1 0.1%

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Due to loss of daily wages		0 0.0%	3 0.3%	0 0.0%	3 0.3%
HIV		27 3.3%	0 0.0%	0 0.0%	27 3.3%
Heart attack		2 0.2%	0 0.0%	0 0.0%	2 0.2%
Initially heavy bacillary load		0 0.0%	0 0.0%	16 2.1%	16 2.1%
Migration		0 0.0%	17 2.1%	0 0.0%	17 2.1%
Not relief from symptoms		0 0.0%	3 0.4%	0 0.0%	3 0.4%
Old age		9 1.1%	0 0.0%	0 0.0%	9 1.1%
Rash all over body-ADR		0 0.0%	1 0.1%	0 0.0%	1 0.1%
Only TB (No associated cause)		22 2.7%	0 0.0%	0 0.0%	22 2.7%
Taken private treatment		0 0.0%	2 0.2%	0 0.0%	2 0.2%
--	688 85.5%	--	--	--	688 85.5%
Total	**--**	**71 8.8%**	**31 3.8%**	**16 2.0%**	**806 100.0%**

Table 4: Causes of death, default and failure

*-Cured treatment completed, transferred out.

DISCUSSION: In present study out of enrolled 806 patients enrolled, 208 (25.8%) had been categorized as cured, 466 (58.4%) as treatment completed, 31 (3.8%) as defaulted, 71 (8.8) as died, 16 (2%) as failure, 14 (1.7%) as lost for follow up i.e. transferred out. It was observed that our regimens produced decline in failure rate, default rate was near expected, death rate was little more. As cure rate was very close to RNTCP objectives, probable reason for good case holding is in study.

Sudipta Pandit et al[3] found that treatment success rate reduced from 90% to 76%, default rate and failure rate increased from7% to 10% and from 3% to 10% respectively.

Our study findings were more or less similar with following studies conducted by S.L. Chadha and R.P. Bhagi,[4] Yatin Dholkia,[5] Usha Damaniand Chaya Desai, R Prasad et al,[6] A.D. Harries,[7] R. Diel and S. Neimann,[8] K. Tsuchida and H. Hoyangi[9] and J. Date and Okita,[10] V. Chandrasekaran et al,[11] J. Ahemad et al,[12] Gurupret Kumar et al,[13] Sudipta Pandit et al.[3]

It was of interest that while alcoholism has appeared to be more common in TB patients than in general population, it had been a not significant predictor of death in present study. The present study revealed that increased mortality risk in patients with pulmonary tuberculosis even after

treatment. It might be worth considering that HIV renders individuals more susceptible to death as in this study 27 deaths are due to HIV.

In present study most of the patients were from lower socioeconomic class. They earned their bread by daily wedges, as they could not spare time to visit DOTS Centre on regular basis thus leading to default. Illiterate patients due to their lack of awareness and ignorance usually tend to default. Once the sputum disappeared or after symptomatic relief after initiation of treatment these patients stopped treatment on their own. Therefore defaulting re-emphasizes the role of health care providers and community in motivating to complete chemotherapy instead of symptom relief therapy. Some people migrate to their native place or for their work and become defaulted. Majority of cases of failure have initial heavy bacillary load. Similar findings have been found in the following studies conducted by K.C. Chang et al,[14] Subodh K. K. Jaggarajumma etal,[15] Katiyar et al,[16] V. Chanchrasekaran et al,[11] N. Pandit et al.[17]

CONCLUSION: There were 233 new sputum smear positive patients enrolled in this study. So sputum conversion rate was 91.84% and cure rate was 80.25%.Out of 506 smear negative and extra-pulmonary patients 462completed treatment hence treatment completion rate was 91.30%, Death rate 9.8%, Default rate 5.15%. Failure rate 2.1%, Transfer out rate 1.6%.

Out 806 patients 208 (25.8%) cured, 466 (58.4%) treatment completed, 31 (3.8%) defaulted treatment, 71(8.8%) died, 16 (2%) failed, 14 (1.7%) transferred out. Out of 71 patients who died 8 (1%) died due to alcoholic liver cirrhosis, 27 (3.3%) died due to HIV, 9 (1.1%) died due to old age, 22 (2.7%) died due to tuberculosis, 1 (0.1%) died due to asthmatic bronchitis, 2 (0.2%) died due to heart attack and 2 (0.2%) died due to abdominal Koch and HIV.

Out of 31 patients defaulted, 5 (0.6%) defaulted due to addiction to alcohol, 3 (0.3%) defaulted due to loss of daily wages, 17 (2.1%) defaulted due to migration, 3 (0.4%) defaulted due to not relief from symptoms, 2 (0.2%) defaulted as they started treatment with private practitioner, 1 (0.1%) defaulted due to adverse reaction i.e. rash all over body.

16 (2%) failure were due to initially heavy bacillary load.

*transferred out may be defaulted, may not follow up.

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