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CASE STUDY

Study of Outcome After One Year Follow Up of Tuberculosis Patients After the Completion of Treatment in Tertiary Care Center in Western Maharashtra

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ABSTRACT

Background: Tuberculosis (TB) still remains an important public health problem in India. After completion of treatment, we hardly know that what happened to these cases once they are declared as cured and released in community. Hence the study was conducted to find out the outcomes and factors associated with them.

Material and methods: It was a longitudinal observational study. Patients were followed up for up to one year after completion of the treatment for weight gain, and adverse side effects.

Results: In our study 91 % of the cases were cured, 1.7 % were treatment failure and 2.18 % died. All the cases of recurrent TB were cured. HIV and TB co-infection was found in 15.7 % cases. 85% of patients tolerated the anti-tubercular therapy (ATT) well. The incidence of extra pulmonary TB was 19.2 %. Out of 229 cases 16 failed to gain weight at the end of therapy. The gain in weight was statistically significant (p value <0.001). The adverse outcome was seen in 20 cases.

Conclusion: In our study, 91 % of the cases including 100% of recurrent Tb cases were cured because of newer RNTCP program. The incidence of extra pulmonary TB was higher than the national average. The majority (85%) of patients tolerated the anti-tubercular therapy (ATT) well. Out of 229 cases, only 16 patients failed to gain weight at the end of therapy. The gain in weight was significant predictor of good outcome in treating tuberculosis. The factors like weight gain, age, sex, place of stay or comorbidities were not associated as predictors of poor outcome. However, presence of comorbidity like HIV and Diabetes may be associated with poor outcome but a higher sample size may be required to confirm it.

Key Message: This study highlighted the importance of weight gain after IP in tuberculosis patients on ATT. The extra pulmonary TB is far more common than national average.

Keywords: Tuberculosis, weight gain, HIV-TB coinfection, predictors of outcome.

Introduction:

'Knowing is not enough; we must apply. Willing is not enough; we must do. "Goethe" Tuberculosis (TB) still remains an important public health problem throughout the world contributing to significant morbidity and it is one of the top ten causes of death worldwide and the leading cause of death from a single infectious agent (ranking above HIV/AIDS).^{1,2} The probable causes of increase in TB incidence are poverty, malnutrition, poor living conditions with overcrowding, war, lack of drugs, underfunding of national tuberculosis program (NTP), and non-adherence to program policies. These factors may cause increased transmission of TB bacilli among the community and/or to an increased risk of conversion from latent to overt clinical TB.³ Early diagnosis and proper treatment are necessary to minimize the transmission of TB bacilli and finally to achieve elimination of TB. If TB is detected early and adequately treated with a combination of medicines for 6 to 9 months; the patients become non-infectious and declared cured. The important problems for TB control are human immunodeficiency virus (HIV), diabetes mellitus co-infection and drug resistance.^{4,5}

Besides this, India has huge burden of multi-drug resistant (MDR) TB and extensively drug resistant TB. Most of them are undetected. Even the detected one has to undergo long duration treatment with less compliance and loss to follow up.

After completion of treatment of a case of TB, there is hardly any information on what happened to these cases once they are declared as cured and released in community. Till recent past there was no mechanism to know about their experiences about the program and to suggest program manager for its improvement. Do they suffer excess mortality or are cured forever? What are the Effects of certain factors like Diabetes mellitus, weight gain, treatment adherence, HIV on outcome of these patients who completed treatment. The existing surveillance system lacks the capacity for long term follow up of these cases.

The present study was conducted to describe the outcome of the TB cases one year post

treatment so as to fill in the gap of longterm outcome among TB patients.

Materials and Methods

This was an observational, longitudinal study. All patients reporting to nodal tuberculosis center at the tertiary healthcare center in western Maharashtra were included during the study period from June 2019 to Dec 2019 were included in the study. The sample size was calculated using the following factors: Hypothesized frequency of outcome factor in population (P) = 16% +/- 5 % Confidence limits as 95% of 100 (absolute +/- %) (d): 5%. Sample size was calculated using the

$$\text{formula} = n = \frac{\left(Z_{\frac{1-\alpha}{2}} \right)^2 \cdot p \cdot (1-p)}{d^2}$$

Where Z = 1.96, p = 0.16, d = 0.05. Sample size (n) for 95% confidence levels is 206; taking 10% drop out rate, the final sample size is **227**.

The Institutional ethical committee clearance was obtained vide letter no IEC/Oct/2019 dated 19 Oct 2019. Data collection was done between June 2019 and December 2019 with simultaneous data entry and analysis on MS Excel in a prevalidated proforma. The inclusion criteria were, all patients who completed treatment of tuberculosis one year prior to the date of data collection and willing to participate were included in the study and for the non survivors; available relative was interviewed to ascertain probable cause of death.

The quantitative variables were described in mean and standard deviation (SD) and qualitative variable by number and percentages. The paired "t" test was done to find the difference among weight at two occasions. Linear regression was done to find out the associated factors of the weight change. Logistics regression was done to find out the factors associated with poor outcome the p value of less than 0.05 was taken as significant. The data was analyzed using StataCorp. 2013. Stata Statistical Software: Release 13. College Station, TX: StataCorp LP

Table No 1: Baseline Patient data and disease characteristics (n= 229)

S no	Characteristic (n=229)	Descriptive statistic
1	Age (years)	36.1 (13.9)
2	Sex Female Male	99 (43.2) 130 (56.8)
3	Population Rural Urban	190 (82.9) 39 (17.7)
4	Socioeconomic status I(Income Nil) II(Income less than Rs 10,000) III(Income between Rs 10,000 – Rs 20,000) IV(Income more than Rs 20,000)	114 (49.8) 33 (14.4) 49 (21.4) 33 (14.4)
5	Occupation I (Not Working) II(Students or equivalent) III(sedentary, office workers-supervisors or equivalent) IV(Non clerical staff or equivalent) V(Daily wage worker or equivalent)	78 (34.06) 35 (15.3) 13 (5.7) 66 (28.8) 37 (16.2)
6	Adverse reactions Nil Rash GI* Symptoms [DILI]† Headache	194 (84.72) 22 (9.61) 12 (5.64) 1 (0.44)
7	Associated Co-morbidities Nil HIV Hypothyroid DM Hypertension	186 (81.2) 36 (15.7) 6 (2.62) 12 (5.3) 16 (6.99)

Figures in parentheses indicate percentage, * Gastrointestinal, † Drug induced liver injury

Results:

We analyzed 229 patients who had completed anti tubercular therapy (ATT) and followed them up for 1 year after completion of treatment. The mean age of the patient was 36.19 (\pm 13.9) years (table 1). According to sex distribution 56.8% were male and 43.2% were female. Type of tuberculosis is depicted in **Table no 2**. Outcome of the treatment is depicted in **Table no 3**. All the recurrent cases were cured. Out of 162 new pulmonary TB cases 150 were sputum positive and 12 were sputum negative. Associated co-morbidities mainly HIV, DM, HTN and hypertension were looked for. HIV and TB coinfection found in 15.7 % cases. Adverse reaction due to drugs noted during study is depicted in **table 1**. Majority of the

patients 194/229(85%) tolerated the anti-tubercular therapy (ATT) well. Skin associated symptoms [rash] were found in 22 cases [9.61%]. Drug induced liver injury and gastrointestinal symptoms found in 12 cases [5.6%]. Mean weight at the start of intensive phase was 49.4 kg (\pm 11.3) and at Continuous phase was 53.3 kg (\pm 11). Out of 229 cases 16 failed to gain weight at the end of therapy. The gain in weight was statistically significant (p value <0.001) **figure 1**. On Univariate analysis weight gain was more among males as compared to females. However, the association was not found when adjusted for other factors like age, place of residence and socio-economic status, there was no significant difference.

Table 2: Various Type of Tuberculosis seen in this study

Type of TB	Number (%)
New pulmonary	162 (70.7%)
New extra pulmonary	44 (19.2%)
Recurrent pulmonary	9 (3.9%)
Recurrent extra pulmonary	14 (6.1%)

Table No 3: Treatment Outcome

S No.	Outcome	Number (%)
1.	Total cases	229(100%)
2.	Cured	209(91.26%)
4.	Death	05(2.18%)
5.	Treatment Failure	15(6.55%)

Table3: Predictors of weight change

S No	Characteristics	Unadjusted β	Adjusted β	95% CI Adjusted β	
1	Age	0.02	0.01	-0.02	0.05
2	Sex Female Male	1.2*	0.5	-0.8	1.7
3	Place Urban Rural	1.03	1.03	-0.3	2.4
4	Socioeconomic status I II III IV	(-).03 0.2 0.1	1.1 1.1 1.5	-.7 -.4 -.2	2.8 2.5 3.2

* Significant at 0.05 level

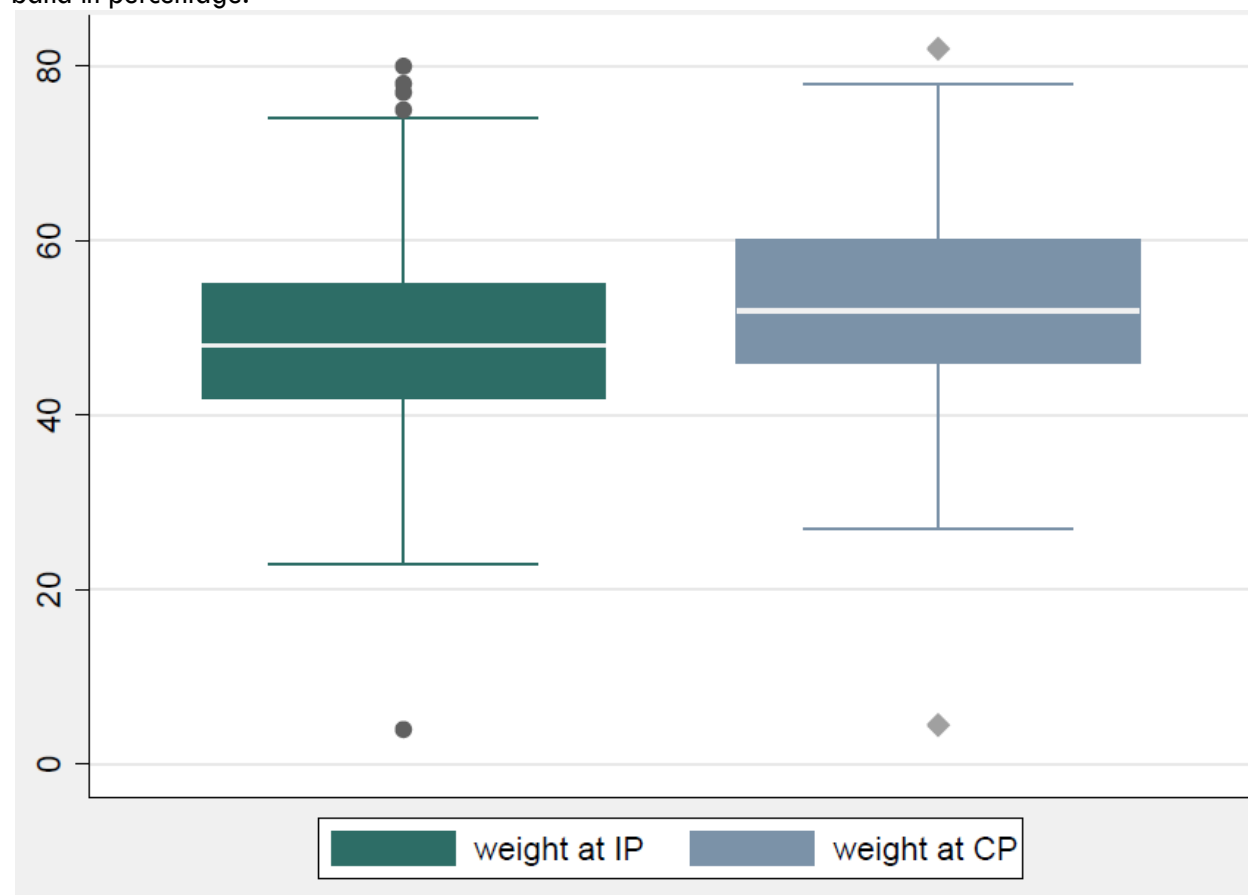
In logistic regression for poor outcome none of the variable like weight gain, age, sex, place of stay or comorbidities was associated. The details

are placed in table 5. However, presence of co-morbidity the odds ratio was 2.5 with 95% confidence interval value (0.9 to 6.9).

Table 5: Predictors of poor outcome

Sno	Characteristics	Unadjusted OR	95% CI	
1	Sex Male Female	(Ref) 0.8	0.3	2.2
2	Residence Rural Urban	(Ref) 2.3	0.8	6.3
3	Co morbidities No Yes	(Ref) 2.5	0.9	6.9
4	Weight At IP	0.9	0.9	1
5	Weight Change Weight change	1	0.9	1.1

Figure 1 Boxplot: X axis showing weight at Intensive and Continuation Phase where Y axis showing weight band in percentage.



Discussion

In India, TB is still continued to be an ongoing growing epidemic day by day. Present study aimed at looking into the outcome after one year follow up in tuberculosis patients after the completion of treatment in tertiary care hospital and to throw more light on grass root level as to whether the patients occupation, area of residence, any adverse effect during ATT, hospitalization during ATT, has any effect on the outcome, adherence to treatment, and weight gain pattern. Various studies have highlighted the fact that dominance of disease is in the middle age group patients which greatly has an impact on the economy of the family.⁷In the present study more number of cases were male. Similar results were seen in study by Chennaveerappa PK et al⁸, K Okanurak et al ⁹, in Thailand and in Hamburg study by R Diel, S Niemann¹⁰. Mir Azam Khan et al¹¹, reported equal number of cases in both sexes.¹⁰Since males are exposed more to external environment than female patients, there is increased burden on the male population. This study showed

that new pulmonary cases were 162/229 (70.7%) and new extra pulmonary cases were 44/229 (19.2%), This data differs from the national figure which states that 85-90% of cases are pulmonary tuberculosis and 10- 15% of cases are extra pulmonary tuberculosis¹².

The association between TB and malnutrition is well recognized. As cell-mediated immunity is the key host defence against TB, malnutrition is, therefore, an important risk factor for the development of TB. In our study mean weight at the start of intensive phase was 49.4 kg (± 11.3) and at continuous phase was 53.3 kg (± 11). The gain in weight was statistically significant (p value < 0.001) (**Figure 1**). Similar results were observed in a study conducted by Vasantha et al. in Tiruvallur district, Tamil Nadu, India. Vasantha et al. observed that the average gain in weight was 3.22 kg among smear-positive cases registered under DOTS and concluded that there is an association between gain in weight with DOT and cure of the patients.¹³ Lack of weight gain with TB treatment has been associated with treatment failure.

In this study 16/229(6.98%) patients failed to gain weight and at the same time had poor outcome. The effect of TB therapy on weight may be confounded by inadequate nutritional intake. A study from Tanzania found that patients had improvement in weight during TB treatment, but these improvements only persisted as long as the patients remained hospitalized, which was likely due to better nutritional intake during hospitalization.¹⁴ The dual tuberculosis (TB) and human immunodeficiency virus (HIV) epidemics are major public health and clinical problems which adversely affect socio-economic development. In tandem, HIV infection and TB create a deadly synergy. HIV and TB interact synergistically, speeding the progression of illness and increasing the likelihood of death. The presence of HIV enhances the reactivation and progression of latent *Mycobacterium tuberculosis* to overt TB disease, and having TB disease accelerates HIV disease progression.¹⁵ It also alters the clinical presentation of TB and complicates the treatment follow-up. In the present study, HIV and TB coinfection was found in 15.7 % cases which was associated with poor outcome than normal cases in terms of cure, weight gain, and hospitalization free period. However, it was 10% in the study by Gebremariam G, et al.¹⁶ In our study, 91 % of the cases were cured, 1.7 % were treatment failure and 2.18 % died. These results are almost similar to the study done by Chennaveerappa PK et al.⁸ When compared to our study treatment outcome was poor in a study done by Moharana et al.¹⁷ Among 23 retreatment cases treatment outcome was, 23 (100%) patients got cured. Treatment outcome was higher in our study

when compared to a study done by S.L. Chadha and R.P. Bhagi.¹⁸ This study documented that the incidence of extra pulmonary tuberculosis is higher as compared to the national average. Weight gain after induction phase of ATT was a predictor of good treatment outcome. The weight gain is not associated with place of residence or socioeconomic status.

Conclusion

In our study, 91 % of the cases including 100% of recurrent Tb cases were cured because of newer RNTCP program. The incidence of extra pulmonary TB was higher than the national average. The majority (85%) of patients tolerated the anti-tubercular therapy (ATT) well. Out of 229 cases, only 16 patients failed to gain weight at the end of therapy. The gain in weight was significant predictor of good outcome in treating tuberculosis. The factors like weight gain, age, sex, place of stay or comorbidities were not associated as predictors of poor outcome. However, presence of comorbidity like HIV and Diabetes may be associated with poor outcome but a higher sample size may be required to confirm it.

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