

STUDY OF WEIGHT VARIATION DURING ANTI-TUBERCULOSIS TREATMENT IN TUBERCULOSIS PATIENTS PUT ON DOTS IN RNTCP IN CENTRAL INDIA

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ABSTRACT

BACKGROUND

Tuberculosis remains a global public health problem and major cause of death from a single infectious agent among adults in India and other developing countries.

The aim of this study is to observe weight variation during anti-tuberculosis treatment in patients put on DOTS in RNTCP.

MATERIALS AND METHODS

This is a retrospective study of diagnosed TB patients from all age groups, attending OPD of various departments at LN Medical College and JK Hospital, Bhopal, MP (India) from January 2012 to October 2015.

RESULTS

Out of total 375 patients, distribution of patients were as follows, 53.87% (202/375) males, 46.13% (173/375) females, 83.20% (312/375) category I and 16.80% (63/375) category II, 91.46% (343/375) gained weight, 4.27% (16/375) weight remained constant and 4.27% (16/375) lose weight. Age group wise maximum percentage of patients who gained weight was 96.30% in age group of 0 - 14 years, whereas maximum percentage of patients suffering weight loss was 5.00% in age group above 45 years.

CONCLUSION

Treatment success rate found higher 91.46% (343/375) in those patients who gained weight. In the present study, higher weight gain (96.30%), higher successful treatment (98.18%), lower default rate (1.81%) and lower weight loss (1.85%) observed in age group of 0 - 14 years, whereas lower weight gain (93.3%), lower successful treatment (65.21%), higher default rate (14.13%), higher death rate (13.04%) and higher weight loss (5.00%) in age above 45 years.

KEYWORDS

Weight Variation, Anti-Tuberculosis Treatment, RNTCP, DOTS.

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BACKGROUND

Tuberculosis (TB) remains a major global public health problem and major cause of death from a single infectious agent among adults in India and developing countries.^[1,2,3] The problem is further compounded by the emergence of HIV, Diabetes and DRTB. According to WHO 6.1 million TB cases reported in 2013, out of which 5.7 million cases were newly diagnosed and another 0.4 million were already on treatment.^[4] The cases of TB are highest in Asia and Africa. India and China together account for approximately 40% of the world's TB cases.^[2] The burden of TB in India is the highest accounting for one-fifth (21%) of the global

incidence.^[5] Every year 1.8 million new cases occur in India, of which 0.8 million are infectious.^[6] As per Revised National Tuberculosis Control Programme (RNTCP) 2011 in Madhya Pradesh, there were 90,764 cases registered for TB.^[7] Tuberculosis is the archetypal wasting disease. The association of TB and nutritional status of patients has long been evident as older terms were used for TB such as the Greek term "phthisis" or "to waste away."^[8] One study reported that moderate and severe malnutrition was a risk factor associated with early death during TB treatment in rural areas of Malawi.^[9] Some studies have reported that weight loss should be considered as clinically relevant.^[10,11,6,12,13] Some studies have suggested an association between meagre weight gain during TB therapy add risk of poor treatment outcome.^[10,6,12]

In India, National Tuberculosis Control Programme (NTP) was launched in 1962. NTP was integrated and implemented through the General Public Health Services.^[14] NTP could not achieve the objective because of low priority, managerial weakness, over dependence on x-ray chest for diagnosis and inadequate funding. In order to overcome the short comings in the NTP, the programme was revised jointly by WHO and Government of India in 1992.

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WHO declared TB, a global health emergency in April 1993.^[6] The Revised National Tuberculosis Programme (RNTCP) has been implemented in 1993, guided by WHO and supported by world bank.^[15] A five points strategy known as Directly Observed Treatment Short Course (DOTS) was launched in India in a phased manner under RNTCP in 1997 with objective of cure rate not less than 85% of infectious TB cases and at least 70% detection of new cases through quality sputum microscopy.^[2,3] With this background, we conducted this retrospective study.

MATERIALS AND METHODS

Present study was retrospectively conducted at LN Medical College and JK Hospital, Bhopal, a tertiary care centre among patients who were registered for treatment of category I and II under DOTS in RNTCP from nearby urban, rural areas and some other districts, between January 2012 and October 2015.

The data had been obtained from DOTS treatment cards, RNTCP referral register, patient record sheet of hospital, lab register and then used for analysis. Body weight of all patients included in this study was recorded in kilogram (kg) at different interval including at time of starting of ATT and at end of treatment. Other variables of interest included in the analysis were sex, age, category (I and II) of patients, types of TB (sputum positive PTB, sputum negative PTB and EPTB) and treatment outcome, etc.

Inclusion Criteria

All patients registered as a case of category I and II tuberculosis.

Exclusion Criteria

Patients having comorbid disease like HIV and DRTB.

The patients had been treated with standard regimens of ATT drugs as provided by Government of India through RNTCP until completion of full course for both categories of patients. During initial intensive phase, all doses of weekly drug pack were administered in front of DOTS provider or health worker thrice weekly followed by continuation phase during this phase first dose of weekly drug pack administered in front of DOTS provider or health worker and rest two doses of weekly drug pack given to patients to be taken at their home as per protocol of RNTCP.

Data were scrutinised and cross checked twice in order to ensure accuracy, then corrected for any missing information.

RESULTS

Among total 453 patients, 375 patients were found eligible for the present study, whose body weight records were available at the time of initiation of treatment and at the end of treatment.

| | Weight Gain % (No.) [91.46% (343)] | Weight Constant % (No.) [4.27% (16)] | Weight Loss % (No.) [4.27% (16)] | Total [375] |
|----------|--|--|--|-----------------------|
| CAT - I | 92.62% (289) | 3.85% (12) | 3.53% (11) | 83.20% (312) |
| CAT - II | 85.71% (54) | 6.35% (4) | 7.94% (5) | 16.80% (63) |
| Male | 95.54% (193) | 2.48% (5) | 1.98% (4) | 53.87% (202) |

| | | | | |
|---------------------|---------------------|-------------------|-------------------|-----------------|
| Female | 86.70% (150) | 6.36% (11) | 6.94% (12) | 46.13% (173) |
| Cured | 92.90% (131/141) | 3.55% (5/141) | 3.55% (5/141) | 37.60% (141) |
| Treatment completed | 90.60% (212/234) | 4.70% (11/234) | 4.70% (11/234) | 62.40% (234) |

Table 1. Weight Variation in Different Group of TB Patients

Out of total 375 patients, distribution of patients were as follows, 53.87% (202/375) males, 46.13% (173/375) females, 83.20% (312/375) category I and 16.80% (63/375) category II, 91.46% (343/375) gained weight, 4.27% (16/375) weight remained constant and 4.27% (16/375) lose weight. Weight variation in the form of weight gain, weight constant and weight loss were observed as follows; 92.62% (289/312), 3.85% (12/312) and 3.53% (11/312) respectively in category I, 85.71% (54/63), 6.35% (4/63) and 7.94% (5/63) respectively in category II, 95.54% (193/202), 2.48% (5/202) and 1.98% (4/202) in male patients, whereas 86.70% (150/173), 6.36% (11/173) and 6.94% (12/173) in female patients.

Among total 453 patients the overall treatment outcomes were as follows; 82.78% (375/453) treatment successful, 31.13% (141/453) cured, 51.66% (234/453) completed treatment, 7.73% (35/453) defaulted, 4.19% (19/454) failed, 0.22% (1/453) relapse, 3.97% (18/453) died and 1.10% (5/453) transferred out.

| | 0 - 14 Years % (No.) [14.40% (54)] | 15 - 45 Years % (No.) [69.60% (261)] | Above 45 Years % (No.) [16.00% (60)] | Total % (No.) [375] |
|-----------------|--|--|--|----------------------------------|
| Cat - I | 16.67% (52) | 67.63% (211) | 15.70% (49) | 83.20% (312) |
| Cat - II | 3.17% (2) | 79.35% (50) | 17.48% (11) | 16.80% (63) |
| Male | 15.84% (32) | 63.86% (129) | 20.30% (41) | 53.87% (202) |
| Female | 12.71% (22) | 76.31% (132) | 10.98% (19) | 46.13% (173) |
| Weight Gain | 96.30% (52) | 90.04% (235) | 93.33% (56) | 91.46% (343) |
| Weight Constant | 1.85% (1) | 5.36% (14) | 1.67% (1) | 4.27% (16) |
| Weight Loss | 1.85% (1) | 4.60% (12) | 5.00% (3) | 4.27% (16) |

Table 2. Age Group Wise Distribution of Category, Sex and Weight Variation

Maximum number of patients 69.60% (261/375) were registered in age group of 15 - 45 years, whereas minimum number of patients 14.40% (54/375) were registered in age of 0 - 14 years. Maximum number of males and females patients were 63.86% (129/202) and 76.31% (132/173) registered in age group of 15 - 45 years. Age group wise maximum percentage of patients gained weight was 96.30% (52/54) in age group of 0 - 14 years, whereas maximum percentage of patients suffered weight loss 5.00% (3/60) observed in age group above 45 years and maximum percentage of patients with constant weight 5.36% found in age group of 15 - 45 years.

| | Weight Gain Range [% (No.)] | | | |
|---------------------|------------------------------|-------------------------------|------------------------------------|-----------------|
| | 0 - 2 kg [20.99% (72)] | 3 - 4 kg [30.02% (103)] | Above 4 kg [48.99% (168)] | Total [343] |
| Male | 18.13% (35) | 29.02% (56) | 52.85% (102) | 56.27% (193) |
| Female | 24.67% (37) | 31.33% (47) | 44.00% (66) | 43.73% (150) |
| Cat - I | 22.49% (65) | 28.03% (81) | 49.48% (143) | 84.26% (289) |
| Cat - II | 12.96% (7) | 40.74% (22) | 46.30% (25) | 15.76% (54) |
| Cured | 16.03% (21) | 22.90% (30) | 61.07% (80) | 38.19% (131) |
| Treatment Completed | 24.06% (51) | 34.43% (73) | 41.51% (88) | 61.81% (212) |

Table 3. Weight Gain Range Wise Distribution in Different Groups of Category, Sex and Treatment Outcome Categories

Overall weight gain (in kilogram) range wise distribution of 343 patients were as follows: 20.99% (72/343), 30.02% (103/343) and 48.99% (168/343) in weight group of 0 - 2 kg, 3 - 4 kg and above 4 kg respectively. Distribution of total 289 patients of category I who gained weight were as follows: 22.49% (65/289), 28.03% (81/289) and 49.48% (141/289) in gained weight group of 0 - 2 kg, 3 - 4 kg and above 4 kg respectively. Distribution of total 54 patients of category II who gained weight were as follows: 12.96% (7/54), 40.74% (22/54) and 46.30% (25/54) in gained weight groups of 0 - 2 kg, 3 - 4 kg and above 4 kg respectively. Sex wise distribution of patients who gained weight in range of 0 - 2 kg, 3 - 4 kg and above 4 kg were 18.13% (35/193), 29.02% (56/193) and 52.85% (102/193) respectively were males, whereas 24.67% (37/150), 31.33% (47/150) and 44.00% (66/150) respectively were females.

Distribution of total 141 exclusive sputum smear positive patients were as follows; 58.16% (86/141) males, 41.84% (59/141) females, 70.92% (100/141) category I and 29.08% (41/141) category II. Distribution of weight gain, weight constant and weight loss respectively were as follows; 96.00% (96/100), 2.00% (2/100) and 2.00% in category I, 85.36% (35/41), 7.32% (3/41) and 7.32% (3/41) category II, 95.12% (78/82), 2.44% (2/82) and 2.44% (2/82) in males, 89.83% (53/59), 5.08% (3/59) and 5.08% (3/59) in females.

In cured group 92.90% (131/141) patients gained weight, out of which 61.07% (80/131) gained weight above 4 kg, whereas in treatment completed group 90.60% (212/234) patients gained weight, out of these only 41.51% (88/212) gained weight above 4 kg.

Distribution of average weight gain were observed as follows: 4.39 kg (1505 kg/343 patients) in overall study patients, 4.34 kg (1533 kg/289 patients) in category I and 4.67 kg (252 kg/54 patients) in category II patients. Age group wise maximum average weight gain found in category I patients was 4.74 kg (218 kg/46 patients) in age group of above 45 years, whereas in category II 5.00 kg (10 kg/2 patients) found in age group of 0 - 14 years.

Overall weight variations in this study were ranged from weight loss of 8 kg to a weight gain of 16 kg in category I

patients, whereas it ranged from weight loss of 6 kg to weight gain of 16 kg in category II.

DISCUSSION

Weight assessment might be an easily available low cost tool to predict outcome among patients receiving ATT in resource constrained setups.^[16] Present study also showed association between weight variation during treatment and TB treatment outcome. Treatment success rate found higher 91.46% (343/375) in those patients who gained weight, but very lower 4.27% (16/375) each in patients whose weight were either constant or reduced during treatment. Similar findings were observed in an Indian study.^[12] Awal Khan et al reported that the patients who were either underweight at time of diagnosis or gained weight less than 5% during initial two months of treatment were associated with an increased risk of relapse.^[10]

Present study highlights the need of regular treatment and keeping body weight normal or required weight gain during treatment for better treatment outcome, which may be helpful to prevent the development of category II or DRTB. It is a suggestion that Government should also provide high calorie diet to patients along with ATT under DOTS in RNTCP.

In present study 92.62% (289/312) patients gained weight in category I, whereas 85.71% (54/63) in category II. Similar findings were also observed in an Indian study.^[12] In this study, higher proportion of males (53.87%) were observed as compared to females (46.13%). Similar findings were reported from different part of India including studies at Aurangabad (62.4%), Delhi (67.6%), Nagpur (69.50%) and South India.^[12,8,3,17] In our study 46.13% (173/375) female patients were registered, while 30.49%, 32.40% and 37.60% female patients were registered respectively at Nagpur, Delhi and Aurangabad.^[8,3,17]

In present study, higher weight gain (96.30%), higher successful treatment (98.18%), lower default rate (1.81%) and lower weight loss (1.85%) observed in age group of 0 - 14 years, whereas lower weight gain (93.3%), lower successful treatment (65.21%), higher default rate (14.13%), higher death rate (13.04%) and higher weight loss (5.00%) in age above 45 years.

One study reported that average weight gain at the end of therapy was observed to be 3.2 kg, in another study reported to be 3.3 kg,^[12] whereas in present study 4.39 kg observed.

Present study showed overall 3.97% patients died during the treatment period, which coincide with national average of 4.00%^[18] and higher death rate (13.04%) was observed in patients above 45 years of age, similar observation was seen in study done at Chennai.^[12]

Dense population, little health awareness, incomplete treatment, increasing trend of nuclear family, lesser intake of normal balance diet, social stigma to attend DOTS centre and lesser pre-employment health check-up of domestic/office helper are major risk factors for TB, which eventually affect individual family condition and economy of country as well.

Further studies with greater sample size are needed to corroborate our findings.

Present study has several limitations being it is a retrospective study and patients with unknown status of

nutrition, education and other immunosuppressive comorbid diseases like diabetes, cancer, chemotherapy and CKD, etc.

CONCLUSION

Treatment success rate found higher 91.46% (343/375) in those patients who gained weight. Higher percentage of weight gain observed in male and category I patients in comparison to other group of patients, i.e. female and category II. Overall weight gain (in kilogram) range wise distribution of 343 patients were as follows: 20.99%, 30.02% and 48.99% in weight group of 0 - 2 kg, 3 - 4 kg and above 4 kg respectively.

Higher weight gain (96.30%), higher successful treatment (98.18%), lower default rate (1.81%) and lower weight loss (1.85%) observed in age group of 0 - 14 years, whereas lower weight gain (93.3%), lower successful treatment (65.21%), higher default rate (14.13%), higher death rate (13.04%) and higher weight loss (5.00%) in age above 45 years. Patient's age group above 45 years need for more evaluation to rule out other risk factors including poor nutritional status, diabetes, obesity, cancer, HIV, renal disease, organ transplant, chemotherapy, cardiac disease, etc.

Being this is a retrospective study, it has few limitations as unable to get record related to diet habits, comorbidities, addiction and treatment history of steroids, etc. of registered patients.

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List of Abbreviations

TB: Tuberculosis.
 RNTCP: Revised National Tuberculosis Control Programme.
 DOTS: Directly Observed Treatment Short course chemotherapy.
 EPTB: Extra-pulmonary tuberculosis.
 PTB: Pulmonary tuberculosis.
 HIV: Human Immunodeficiency Virus.
 ATT: Anti-Tuberculosis Treatment.
 CKD: Chronic Kidney Disease.
 DM: Diabetes Mellitus.

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