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Original Research Article

Does nutritional support under programmatic settings result in weight and body mass index changes among tuberculosis patients? Evidence on the impact of nutritional support through Pradhan Mantri Tuberculosis Mukt Bharat Abhiyan under national tuberculosis elimination programme from Ramgarh district of Jharkhand

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ABSTRACT

Background: To increase community participation in tuberculosis (TB) elimination efforts, the government of India has launched 'Pradhan Mantri TB Mukt Bharath Abhiyan' (PMTBMBA) under the national TB elimination programme. The scheme allows interested parties (Ni-kshay mitras) to offer nutritional support to TB patients. This study aims to understand the impact of such a support in improving weight and body mass index (BMI) among TB patients as most available evidence comes from research settings.
Methods: This is a retrospective cross-sectional study carried out in Ramgarh district of Jharkhand, India, for the period first quarter 2023. Relevant data was extracted from Ni-kshay web portal and TB treatment cards. The data is analyzed using excel 365.
Results: Of the 114 participants, 69 received nutritional support during the entire duration of treatment and 45 received support partially. Single factor ANOVA on weight and BMI gain revealed statistically significant difference in mean weight/BMI between the two groups with $F(1, 110)=35.4660$, $p=3.16\times10^{-08}$ and $F(1, 110)=22.9994$, $p=5.12\times10^{-06}$. Correlation analysis showed a moderate correlation between the number of nutritional kits received and the weight/BMI gain with correlation coefficients $r=0.5$, $p=1.07\times10^{-07}$ and $r=0.4$, $p=1.65\times10^{-05}$ respectively.
Conclusions: The study concludes that the impact of nutritional supplementation in programmatic setting is comparable with that of implementation research study settings.

Keywords: Pradhan mantri TB mukt bharath abhiyan, Ni-kshay mitra, Nutritional support in TB

INTRODUCTION

India accounts for 26% of global TB burden.[1] To decrease the TB disease burden, the government of India has accelerated its effort to end TB in India and transformed national TB control programme into an elimination programme. But government efforts are meaningless if there is no participation of civil society in it. So, to increase community participation in TB elimination efforts in country, honorable president of India has

launched 'community support to TB patients-PMTBMBA in September 2022. Under this scheme, individuals, co-operative societies, corporates, elected representatives, institutions, NGOs, political parties can come forward as Ni-kshay mitras and support in TB elimination efforts. Ni-kshay means 'without TB' and mitra means 'a friend' in ancient Indian language Sanskrit.

Interested entities can register as Ni-kshay mitra through the TBC India and the Ni-kshay web portals of the government of India. Every registered Ni-kshay Mitra go through a verification process by the TB program team before any supportive action can be initiated. This step safeguards the authenticity of Ni-kshay mitras and ensures that the support committed is realistic. Ni-kshay mitras can offer support under the following streams: nutritional support to TB patients, nutritional support to TB patients and families, vocational training to TB patients or families depending on the requirement and support to TB patients in getting additional investigations done which are not available free of cost under the TB programme. Nutritional support to TB patients and families is given prime importance under the scheme as undernutrition has the highest population attributable risk (34.2%) for TB in India.[2] Individual Ni-kshay mitras are eligible to adopt single patients. Other Ni-kshay mitras are expected to adopt all the TB patients belonging to a health facility or a larger geographical area like revenue blocks, urban wards, districts, or the state. Support is to be ensured for a minimum duration of six months.[3]

Ramgarh district of Jharkhand has 21 Ni-kshay mitras. Two corporates and the remaining nineteen individual Ni-kshay mitras. Three revenue blocks are adopted by the two corporates. Individual Ni-kshay mitras have adopted number of patients ranging from one to five. All Ni-kshay mitras have committed to give nutritional support to TB patients only. Individual Ni-kshay mitras have committed their support for a duration of 6 months and corporates, for a period of one year. Nutritional support generally included chickpeas (1.5 kg), pigeon peas (1.5 kg), red lentil (1.5 kg), ground nuts (0.5 kg), soyabean (300 gm) and jaggery (1 kg) though there could be minor variations among different Ni-kshay mitras.[4] There are evidence available on impact of nutritional support in improving weight and BMI among TB patients and reducing TB mortality in research settings.[5] Study aims to understand impact of nutritional support in improving weight and BMI among TB patients in programmatic settings.

METHODS

This was a retrospective cross-sectional study carried out in Ramgarh district of Jharkhand state in India. With the permission of the district TB Officer, district level data on nutritional support to TB patients through PMTBMBA was obtained for the first quarter of 2023. The first quarter of 2023 was selected as the period of study because PMTBMBA was launched in September 2022 and the initiative was getting streamlined in the initial months following the launch. Subsequent quarters were omitted as treatment outcomes of all the patients in the later quarters were not available with NTEP team at the point of data analysis and a successful outcome was mandated for patients to be included in the study. All patients in the selected cohort were considered for the study and further included or excluded in the study based on the inclusion and exclusion criteria as follows. All TB patients who received at least one nutritional kit through PMTBMBA were included in the study if they were HIV negative, had a drug sensitive TB (DSTB), had a successful treatment outcome, and had a duration of treatment of six months. Patients who are HIV positive, with drug resistant TB (DRTB), without treatment success and have not received nutritional support through PMTBMBA were excluded from the study. DSTB patients who fulfilled other inclusion criteria but had a treatment duration of more than 6 months were excluded from the study to keep the uniformity while measuring the weight at the beginning and end of treatment. Patients' demographic and clinical data were downloaded from Ni-kshay web portal in excel format. Data on weight at the beginning and end of TB treatment were collected from TB Treatment Cards and entered in excel format manually. The data is analyzed using excel 365. To understand the statistical significance of weight and BMI changes among the study population, single factor ANOVA and correlation analysis were done. The study did not collect primary data from any patients and does not reveal any personal identifiers. So, individual patient consent is considered unnecessary for the study.

RESULTS

Ramgarh district provided TB treatment to 310 patients in the first quarter of 2023. Of which 114 patients fulfilled all the inclusion criteria and were included in the study.

Baseline profile

As shown in Table 1, a total of 69 participants received nutritional support during the entire duration of treatment and 45 participants received one to four kits containing nutritional support. Female participants constituted 29.8 per cent (n=34) of the study population and the remaining participants were male. There were no transgender participants in the study. The median age of the study population is 37 years with 95% CI: 34 to 39.9 years and inter quartile range (IQR) 25 to 50.25 years. Participants who received partial nutritional support during TB treatment were younger with a median age of 35.5 years with 95% CI: 31 to 40 years as compared to those who received nutritional support throughout the treatment. The median age of the latter is 40 years with 95% CI: 36.1 to 43.9 years. Participants with pulmonary TB constituted 81.6 per cent (n=93) and the remaining had extra pulmonary disease. Participants with bacteriologically confirmed TB disease constituted 75.4% (n=86) and the remaining had no bacteriological confirmation of the disease. Diabetes mellitus was present in 11.4 per cent

(n=13) of the participants and the remaining were non-diabetic. Burden of Diabetes Mellitus was lower among those who received partial nutritional support during TB treatment with only 6.7 per cent (n=3) of the participants with diabetes as compared to those who received nutritional support throughout the treatment. The proportion of participants with diabetes among the latter is 14.5 per cent (n=10). Most of the participants sought TB care in the public sector with only 2.6 percent (n=3) participants seeking care in the private sector.

Analysis of weight changes during TB treatment

Table 2 compares the weight characteristics of the participants in two groups based on whether they had received nutritional support completely during TB treatment or received partial support. Initial weight is comparable in both the groups with mean weight (95% CI) of 44.3 (42.1-46.4) kg for the group which received complete nutritional support and for those who received partial support, it is 44.1 (40.9-47.1) kg. Weight at the end of treatment is higher in the former group with a mean (95% CI) of 49.2 (47.0-51.3) kg and in the latter group, 47.2 (44.1-50.2) kg. Weight gain is also better in the first group with a mean (95% CI) of 4.9 (4.5-5.3) kg and in the second group with 3.2 (2.9-3.4) kg. Percentage weight gain (95% CI) is 11.1 (3.7-18.5) in the former and 7.3 (1.2-13.4) in the latter groups. Single factor ANOVA was performed to compare the initial weight, weight at the end of treatment and weight gain among the two groups in three separate exercises. The single factor ANOVA on the initial weight revealed no statistically significant difference in mean weight between the two groups with F (1, 110)=0.0132, p=0.91. The single factor ANOVA on the weight at the end of treatment also revealed no statistically significant difference in mean weight between the two groups with F (1, 110)=1.0462, p=0.31. But single factor ANOVA on the weight gain revealed statistically significant difference in mean weight between the two groups with F (1, 110)=35.4660, $p=3.16\times10^{-08}$. Correlation analysis was performed to understand the relationship between the number of nutritional kits received and the weight gain. The analysis showed a moderate correlation between the two variables with correlation coefficient (r) = 0.5, $p=1.07\times10^{-07}$.

Analysis of BMI changes during TB treatment

Table 3 compares the BMI characteristics of the participants in two groups based on whether they had received nutritional support completely during TB treatment or received partial support. Initial BMI is lower in the group which received complete nutritional support during TB treatment, with mean (95% CI) BMI of 18.0 (17.3-18.8) kg/m^2 and the same for those who received partial support is 18.8 (17.7-19.8) kg/m^2. BMI at the end of treatment is comparable in both the groups with a mean (95% CI) of 20.0 (19.3-20.8) kg/m^2 and 20.2 (19.1-21.2) kg/m^2 respectively. BMI gain is better in the first group with a mean (95% CI) of 2.0 (1.8-2.2) kg/m^2 and in the second group it is 1.4 (1.3-1.5) kg/m^2. Single factor ANOVA was performed to compare the initial BMI, BMI at the end of treatment and BMI gain during treatment among the two groups in three separate exercises. The single factor ANOVA on initial BMI revealed no statistically significant difference in mean BMI between the two groups with F (1, 110) =1.2721, p=0.26. The single factor ANOVA on BMI at the end of treatment also revealed no statistically significant difference in mean BMI between the two groups with F (1, 110)=0.0368, p=0.85. But single factor ANOVA on the BMI gain revealed statistically significant difference in mean BMI between the two groups with F (1, 110)=22.9994, $p=5.12\times10^{-06}$. Correlation analysis was performed to understand the relationship between the number of nutritional kits received and the BMI gain. The analysis showed a moderate correlation between the two variables with correlation coefficient (r) = 0.4, $p=1.65\times10^{-05}$.

Table 1: Baseline characteristics.

Baseline characteristics		Received nutritional support for the entire duration of treatment: received 6 food baskets, (n=69) (%)	Received nutritional support partially during treatment: received 1-4 food baskets, (n=45) (%)	Total, (n=114)
Sex	Female	21 (30.4)	13 (28.9)	34 (29.8)
	Male	48 (69.6)	32 (71.1)	80 (70.2)
Age (in years)	Median age (95% CI)	40.0 (36.1-43.9)	35.5 (31.0-40.0)	37.0 (34.0-39.9)
	IQR	25.5-52.5	22-45.5	25-50.25
Site of disease	Extra pulmonary	11 (15.9)	10 (22.2)	21 (18.4)
	Pulmonary	58 (84.1)	35 (77.8)	93 (81.6)
Status of bacteriological confirmation	No	18 (26.1)	10 (22.2)	28 (24.6)
	Yes	51 (73.9)	35 (77.8)	86 (75.4)
DM status	Diabetic	10 (14.5)	3 (6.7)	13 (11.4)
	Non-diabetic	59 (85.5)	42 (93.3)	101 (88.6)
Health sector	Public	68 (98.6)	43 (95.6)	111 (97.4)
	Private	1 (1.4)	2 (4.4)	3 (2.6)

Table 2 Analysis of weight changes during TB treatment.

Variables		Received nutritional support for entire duration of treatment: received 6 food baskets, (n=69)	Received nutritional support partially during treatment: received 1-4 food baskets, (n=45)
Initial weight	Mean (95% CI)	44.3 (42.1-46.4)	44.1 (40.9-47.1)
End of treatment weight		49.2 (47.0-51.3)	47.2 (44.1-50.2)
Weight gain		4.9 (4.5-5.3)	3.2 (2.9-3.4)
Percentage weight gain (95% CI)		11.1 (3.7-18.5)	7.3 (1.2-13.4)
Analysis of variance: single factor			
Variables	**F crit**	**F (1, 110)**	**P value**
Initial weight	3.9274	0.0132	0.91
End of treatment weight		1.0462	0.31
Weight gain		35.4660	3.16×10^{-08}
Correlation analysis of number of nutritional kits received and weight gain			
Correlation coefficient (r)		0.5	1.07×10^{-07}

Table 3: Analysis of BMI changes during TB treatment.

Variables		Received nutritional support for the entire duration of treatment: received 6 food baskets, (n=69)	Received nutritional support partially during treatment: received 1-4 food baskets, (n=45)
Initial BMI	Mean (95% CI)	18.0 (17.3-18.8)	18.8 (17.7-19.8)
End of treatment BMI		20.0 (19.3-20.8)	20.2 (19.1-21.2)
BMI gain		2.0 (1.8-2.2)	1.4 (1.3-1.5)
Analysis of variance: single factor			
Variables	**F crit**	**F (1, 110)**	**P value**
Initial BMI	3.9274	1.2721	0.26
End of treatment BMI		0.0368	0.85
BMI gain		22.9994	5.12×10^{-06}
Correlation analysis of number of nutritional kits received and BMI gain			
Correlation coefficient (r)		0.4	1.65×10^{-05}

DISCUSSION

This is one of the first studies conducted to understand the impact of nutritional support to tuberculosis patients on weight and body mass index in programmatic settings in India. The general profile of patients belonging to the group that received nutritional support during the entire duration of treatment and the other group that received partial nutritional support during treatment are comparable though patients belonging to the latter group are relatively younger and with a lesser burden of diabetes mellitus. Weight gain and body mass index improvement among those received nutritional support during the entire duration of treatment are comparable with the results of another study conducted in Jharkhand on the influence of nutritional support to adult bacteriologically confirmed tuberculosis patients on treatment outcomes by Bhargava et al.[5] Another study conducted by Howell et al in Madhya Pradesh, India also found statistically significant weight gain among tuberculosis patients after nutritional interventions.[6] The prior mentioned study by Bhargava et al also found that weight gain was associated with a considerably lower risk for tuberculosis mortality.[5]

A nutritional intervention study conducted in central India by Singh et al found that the mean weight for TB patients increased significantly during each food distribution episode.[7] This corresponds with our study finding of a moderately positive correlation between the number of nutritional kits received and weight-BMI gain. The same study found that the treatment success rate was better among the intervention group as compared to the control group. Another multi-center study conducted among TB patients who were underweight at baseline found that weight gain of 5% or less during the first 2 months of treatment is associated with an increased risk of relapse.[8] Studies have also found that TB patients with a low BMI are at a higher risk of severe disease and delayed sputum conversion. They are also at a risk of malabsorption of anti TB drugs and drug induced liver toxicity.[9] So, more studies need to be conducted to understand how nutritional supplementation influence these factors in programmatic settings.

In response to the emerging evidence on the benefit of addressing undernutrition to reduce TB burden, world health organization (WHO) in its 20213 guideline called for specifically addressing severe undernutrition as part of

TB treatment.[10]A review on the prospect to prevent and manage undernutrition to intensify TB control efforts by Hill et al argues that TB control in low resource and food insecure settings depend partially on addressing undernutrition and demand for stronger policies in this regard from national governments.[11] So, to improve treatment success and reduce disease severity, drug toxicities, relapse, and mortality due to TB, it is important to keep weight and BMI gain as an important target in patient management.

Limitations

Our study has focused on the weight and BMI changes at the beginning and end of TB treatment which spans across a period of six months, further studies need to be conducted to understand the monthly trends in weight and BMI changes among patients given nutritional support in programmatic settings. Also, further studies need to be conducted to understand the impact of nutritional support on disease severity, sputum conversion, anti TB drug metabolism and drug toxicities in programmatic settings. Another topic which needs to be explored is the impact of nutritional supplementation among drug resistant TB patients in programmatic settings.

CONCLUSION

Strong policy decisions on nutritional support to TB patients through national TB programmes in high burden countries will take global efforts to end TB a long way. The step to involve civil society in providing nutritional support to TB patients by the government of India is certainly a welcome step as our study concludes that the impact of nutritional supplementation in programmatic settings is comparable with that of implementation research study settings.

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