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Prevalence of household food insecurity and its associated factors in tuberculosis patients in south India: A cross sectional analysis

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TITLE

Prevalence of household food insecurity and its associated factors in tuberculosis patients in south India: A cross sectional analysis

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ABSTRACT

Objectives

Food insecurity is 'the limited or uncertain availability of nutritionally adequate, safe foods or inability to acquire foods in socially acceptable ways'. A major proportion of Tuberculosis (TB) cases of resource-poor settings experience food insecurity, which impacts treatment adherence and outcomes. We aimed to determine prevalence of household food insecurity and its associated factors in tuberculosis (TB) patients.

Design

This is a cross sectional analysis of secondary data from a cohort study.

Setting

National Tuberculosis Program (NTP) in three districts of south India.

Participants

All newly diagnosed pulmonary TB cases (both smear and culture positive) of the cohort enrolled from October 2015 to October 2018.

Primary Outcome Measures

The proportion of baseline household food insecurity assessed using a validated household food insecurity access scale was summarized as percentage with 95% confidence interval (CI). Possible association of socio-demographic, morbidity and behavioural characteristics with household food insecurity was assessed using chi-squared test, unadjusted prevalence ratios with 95% CI were calculated. The characteristics with p value less than 0.2 in the univariate model were included in multivariable generalized linear model (binomial function and log link) to derive adjusted prevalence ratios (aPR) with 95% CI.

Result

Of total 765 patients, 261 had household food insecurity and the prevalence was 34.1% (95% CI 30.8-37.6%). Mild, moderate and severe food insecurity was found in 17 (2.2%), 67 (8.8%) and 177 (23.1%) TB cases respectively. TB patients who had monthly family income less than INR 3000 (aPR 2.0; 95% 1.3-3.0), Karnofsky score of 60 or less (aPR 1.5; 95% 1.1-1.9) and those who were employed (aPR 1.4; 95% 1.0-2.0) had higher prevalence of household food insecurity.

Conclusions

High level of food insecurity was seen in households of TB cases. Additional food or cash assistance for this sub-group might improve food insecurity and thereby nutritional status.

Key Words

Undernutrition, HFIA scale, Karnofsky score, food assistance, SORT IT

Article Summary

Strengths:

- Use of a validated tool for assessing household food insecurity which allows cross country comparisons.
- We used the data from a prospective cohort study which implemented quality assurance checks for data collection, entry and completeness that would have reduced missing data and data errors.
- Our study included patients identified in the public sector alone and food insecurity levels may be different in patients accessing TB care in the private sector.

Limitations:

- We did not study the sub group of previously treated TB patients in whom levels of food insecurity could be higher due to financial loss caused by repeated episodes of TB.
- The study participants were from selected three districts in south India, so generalisability of the findings is limited.

INTRODUCTION

Tuberculosis (TB) is the leading cause of death from a single infectious agent, ranking above HIV/AIDS and overall, the ninth leading cause of death worldwide. In 2017, there were an estimated 1.3 million TB deaths among HIV-negative people. India contributes roughly 25% of global incident TB cases and there were an estimated 421000 deaths annually due to TB in the year 2017. (1,2) In 2014, World Health Organization (WHO) endorsed the "End TB strategy" in line with the Sustainable Development Goals (SDGs) developed by the United Nations (Goals 1, 2 and 3 deal with action on poverty, hunger and ensuring healthy lives and well-being of people) with a common aim to end the global TB epidemic.(1,3)

Food security is a state in which "all people at all times have both physical and economic access to sufficient food to meet their dietary needs for a productive and healthy life".(4) Catastrophic health expenditure is a common consequence of TB diagnosis, treatment and care which can lead to impoverishment and in turn food insecurity for TB patients. Food insecurity and under-nutrition share a bidirectional relationship with TB; both cause TB and could be consequences of TB. Undernutrition in patients with active TB can lead to worsening of disease, drug toxicity, drug malabsorption and death or relapse of disease. (5–7)

A recent national survey (2016) in Vietnam reported that 22% of households experienced food insecurity during TB treatment, this proportion being as high as 40% among the poorest wealth quintiles.(8) Food insecurity at the household level is common in India and is a strong risk factor for progression of latent infection to active TB in household contacts.(9) TB in India affects poor families and communities disproportionately, with a fourfold higher prevalence in those with a low standard of

living index compared to those with a high standard of living index.(5) Food insecurity is also of greatest significance in households where levels of food insecurity and undernutrition are high at the time of diagnosis. Since food insecurity and under-nutrition can co-exist, patients with TB are unable to regain a normal weight, despite effective treatment.

WHO (2013) in its guidelines 'Nutritional care and support for patients with tuberculosis' recommends assessment of food insecurity among TB cases and addressing the same with suitable packages including food assistance.(3) Recently, Government of India has launched a cash assistance scheme for all TB cases to mitigate costs and improve nutritional status. (10) However, there may be households with more food insecurity that need more food assistance rather than equal assistance to all. In India, studies assessing household food insecurity among TB cases are limited. Therefore, we aimed to determine the level of food insecurity and its associated factors using secondary data from a cohort of pulmonary TB patients in south India.

METHODS

Study Design

This is a cross sectional analysis of secondary data from a cohort study under RePORT India Consortium (Regional Prospective Observational Research for Tuberculosis). Details of the study design have been previously reported. (11–14)

National tuberculosis program (NTP)

The study covers Puducherry district of Union Territory of Puducherry (population~1.3 million) and two adjoining districts of Tamil Nadu i.e. Villupuram (population~3.5 million) and Cuddalore (population~2.6 million). Under the national program (NTP), TB diagnostic and treatment services are delivered through the designated microscopy centres (DMCs) and peripheral health institutions (PHIs) under Tuberculosis units (TUs) as nodal points for TB control activities at sub-district level. Sputum smear microscopy remains the central component of TB diagnosis. Under NTP, both diagnosis and treatment are provided free of cost to the TB patients. On diagnosis of TB, the patients are referred to the nearest PHI for initiation of treatment. Morbidity details (diabetes, HIV) and medication adherence, follow-up details and TB treatment outcomes of these patients are documented in individual TB treatment card.

RePORT International

Regional Prospective Observational Research in Tuberculosis (RePORT) International represents a consortium of regional cohorts (RePORT India, RePORT Brazil, RePORT South Africa, RePORT China, RePORT Philippines and RePORT Indonesia) that are linked through the implementation of a common protocol for data and specimen collection. Objectives and composition of RePORT International are described elsewhere.(15)

One of the five teams under RePORT India, Jawaharlal Institute of Postgraduate Medical Education & Research (JIPMER) Boston Medical Center and Rutgers University has established a pulmonary TB cohort of adults and children ≥ 6 years and their household contacts to identify biomarkers for risk of TB treatment failure and risk of development of TB in household contacts. TB cases diagnosed under NTP in the three districts (Puducherry, Cuddalore and Villupuram) were included in the cohort since 2014. Only newly diagnosed smear and culture positive pulmonary TB cases were included. Details on tobacco use, alcohol use, household food insecurity, severity of TB (Karnofsky score), diabetes status and HIV status were collected at baseline within seven days of initiation of treatment. Based on Karnofsky score patients were categorized on their functional impairment (scale ranges from 0-100). If the score is low, more severe is the illness.

All the above information was recorded in project specific case report forms (CRFs) and these CRFs were scanned and transferred to data coordinating centre at Boston Medical Centre with Verity TeleForm Information Capture System software V10.8 (Sunnyvale, CA, USA), and read and uploaded into a Microsoft Access (Seattle, WA, USA) database. All the filled-in CRFs were checked for completeness by a supervisor on daily basis and periodically by the data manager.

Study population

For this analysis, we included all TB cases of the cohort enrolled from October 2015 to October 2018. Multi drug resistant and extremely drug resistant TB cases at diagnosis were excluded.

Study tool

Household Food Insecurity Access Scale (HFIAS)(4) was used to assess food insecurity in the households in the past 30 days. The scale consists of nine items grouped under three domains: 1) anxiety or uncertainty about the household food supply 2) Insufficient Quality and 3) Insufficient food intake and its physical consequences (4). The respondent is first asked an occurrence question, whether the condition in the question happened at all in the past four weeks (yes or no). If the respondent answers "yes" to an occurrence question, a frequency-of-occurrence question is asked to determine whether the condition happened rarely (once or twice), sometimes (three to ten times) or often (more than ten times) in the past four weeks. Each item is scored on a range of 0 to 3; zero for 'no occurrence' and three for 'often'. The minimum and maximum score for a household are0 and27 respectively. The scores were categorized into four levels of household food insecurity: food secure and mild, moderately and severely food insecure (4)-Annexure 1.

Alcohol Use Disorders Identification Test (AUDIT)-C questionnaire (a modified version of AUDIT) (16) was used to assess the alcohol use among participants.

Data extraction, analysis and statistics

Of total 1229 TB cases enrolled in the cohort, we extracted data for 765 cases excluding two childhood TB cases; the initial 462 cases enrolled were not assessed for household food insecurity and were excluded. Data were extracted from the RePORT India project database for JIPMER site in a de-identified manner and analysed using Stata 12.0 software. The proportion of household food insecurity was summarized as percentage with 95% confidence interval (CI). Possible association of socio-demographic, morbidity related and behavioural characteristics with household food insecurity was assessed using chi-squared test and unadjusted prevalence ratios

with 95% CI were calculated. The characteristics with p value less than 0.2 in the univariate model were included in multivariable generalized linear model (binomial function and log link) to derive adjusted prevalence ratios(aPR) with 95% CI. The variables such as marital status, education, residence, number of earners in the household, HIV status, tobacco use, and alcohol use were not included for multivariate analysis.

Ethics Approval

Ethics approval was obtained from the Institutional Ethics Committee of JIPMER (Ref.No: JIP/IEC/2013/4/194) and Institute Review Board of Boston Medical Center (IRB No: H-32657/7-05-2017) for the cohort study. Written informed consent was obtained from all participants before enrolment. The study protocol for this secondary analysis was reviewed and approved by Ethics Advisory Group of the International Union Against Tuberculosis and Lung Disease (99/18), Paris, France.

Patient and Public Involvement

There was no patient or public involvement.

RESULTS

Of the 765 individuals included in analysis, the mean (standard deviation) age was 44 (14) years; 611 (80%) were males. Socio-demographic characteristics of TB cases are described in **Table-1**. Of total, 131 (17%) participants did not have any formal education, about 77% were employed and 11% had monthly family income less than INR 3000 (~USD 43). Behavioural and disease related characteristics are described in **Table-2**. More than half (58%) were alcohol users (in the previous year) and 30% were current tobacco users. Of total, 470 (61%) were underweight (body mass index <18.5 kg/m2) and five patients (0.6%) were HIV-infected. Karnofsky score was 60 or less (require assistance for routine activities) in 29% of patients.

Overall, 261 patients had household food insecurity and the prevalence was 34.1% (95% CI 30.8-37.6%). Mild, moderate and severe food insecurity was found in 17 (2.2%), 67 (8.8%) and 177 (23.1%) TB cases respectively. Components of food insecurity are described in **Table-3**. Worry or anxiety about not having enough food was reported in 15% of TB households. In 21% of TB households, eating fewer meals in a day due to lack of enough food was reported.

Prevalence of food insecurity in different sub groups is presented in **Table-4**. In adjusted analysis, TB cases who had monthly family income less than INR 3000 (aPR 2.0; 95% 1.3-3.0), Karnofsky score of 60 or less (aPR 1.5; 95% 1.1-1.9) and those who were employed (aPR 1.4; 95% 1.0-2.0) had higher prevalence of household food insecurity.

DISCUSSION

Our study among newly diagnosed pulmonary TB patients in public sector in south India revealed that about one third of TB patients experienced household food insecurity; about one out of four patients experienced severe food insecurity at the time of diagnosis. Prevalence of food insecurity was high in low income groups, employed and those who had severe illness.

Prevalence of food insecurity in the general population of India is also high ranging from 45.5% to 77.2%. (17,18) Hence, household food insecurity among TB patients is common as it can be both a cause and consequence of TB. The national level survey from Vietnam (2016) reported 22% of TB patients experienced household food insecurity; lower levels of 6% were reported among TB patients in Sri Lanka. (8,19)

Food insecurity was twice as high in low income TB households (INR<3000) compared to their higher income counterparts. Catastrophic health expenditure, a consequence of TB diagnosis and treatment can lead to worsening of food insecurity in low income groups during the course of the disease.(5) These subgroups need to be provided additional assistance instead of 'equal for all' food or cash assistance benefits. Since income is usually underreported, identifying such target groups may not be an easy task.

Food insecurity at the household level is a strong risk factor for progression of latent infection to active TB in household contacts. (9,20) Since, food insecurity measures are applicable to all households, a wider approach of reducing food insecurity targeting all household contacts is needed.

In our study, about 60% of the TB patients were underweight. Undernutrition is both an important risk factor for, and a common consequence of TB. In food insecure

households, undernutrition could be an intermediary step in the nutritional pathway of food insecurity leading to morbidity like TB. In India, undernutrition is highly prevalent in patients with TB and the dietary intake of calories is significantly lower (500-700 calories) than recommended. (21) As recommended by WHO, addressing undernutrition through nutritional counselling and support should be considered as part of the standard of care for people with TB. The recently launched "Nikshay Poshan Yojana", a direct benefit transfer scheme by the government of India is a welcome step towards addressing undernutrition. (22) Our study did not include severely ill patients (Karnofsky score<40) and previously treated TB patients in whom undernutrition rates are expected to be high. This may partly explain why our study did not find an association between food insecurity and undernutrition, though previous studies have reported otherwise. (23–26) Also, we have assessed food insecurity at the level of household and body mass index assessed is that of the individual patients. May be the patient's nutrition is maintained at the expense of other family members, so he or she may have had normal BMI.

Several studies support the notion that food insecurity negatively affects treatment adherence. Conditions of food insecurity (lack of adequate food, concern about daily food production) contribute to non-adherence to TB treatment as reported by qualitative studies. (27–29) Hence, identifying food insecurity at the time of diagnosis and linking the patients to food assistance or social security programs is needed. We plan to report the effect of food insecurity on adherence and TB treatment outcomes in a separate paper.

Strengths of the study include use of a validated tool (4) for assessing household food insecurity which allows cross country comparisons. We used the data from a prospective cohort study which implemented quality assurance checks for data

collection and entry that would have reduced missing data and data errors. Our study included patients identified in the public sector alone and food insecurity levels may be different in patients accessing TB care in the private sector. Since, repeated episodes of TB may be a cause for financial loss leading to food insecurity, the levels could be higher in previously treated TB patients and we did not study this sub group. Being a cross sectional analysis, causal relationships of factors with food insecurity cannot be inferred. The study participants were from selected three districts in south India, so generalisability of the findings is limited.

CONCLUSION

To conclude, household food insecurity was experienced by one in three TB patients and this was twice higher in low income groups. Additional food or cash assistance to food insecure TB patients and household contacts will improve the food insecurity and undernutrition.

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COMPETING INTERESTS

The authors have declared that no competing interests exist.

CONTRIBUTION OF AUTHORS

RA: Principal Investigator (PI), conception/ design of the protocol, data capture, development of data capture tool, data analysis / interpretation, drafting / critically reviewing the paper, giving approval for the final version to be published

SS: Acquisition of data, conception/ design of the protocol, revision of manuscript, critically reviewing the paper, giving approval for the final version to be published

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Table 1: Socio-demographic characteristics of individuals with pulmonary tuberculosis (TB) in three districts of South India, 2015-2018. (N=765)

Characteristics	Frequency (%)
Age (in years)	
15-29	130 (17.0)
30-44	229 (29.9)
45-59	292 (38.2)
60 and above	114 (14.9)
Gender	
Male	611 (79.9)
Female	154 (20.1)
Marital Status	
Never Married	132 (17.3)
Married/Living together	567 (74.1)
Separated/divorced/ widowed	66 (8.6)
Education (years of schooling)	
No formal Education	131 (17.1)
1-5	160 (20.9)
6-10	317 (41.4)
>10	157 (20.5)
Employment	
Employed	588 (76.9)
Unemployed	177 (23.1)
Household Income per month (in INR)	
< 3000	80 (10.5)
3000-5000	296 (38.7)
5001-10000	279 (36.5)
>10000	94 (12.3)
Didn't answer	16 (2.0)
Number of individuals in house	
≤3	604 (78.9)

>3	161 (21.1)
Residence*	
Urban	338 (44.2)
Rural	409 (53.4)
Not recorded	18 (2.4)
Number of earners in the household	
None	15 (1.9)
One	509 (66.5)
Two or more	241 (31.6)
Religion	
Hindu	677 (88.5)
Christianity	54 (7.1)
Muslim	32 (4.2)
Others	2 (0.3)

Table 2: Morbidity and behavioural characteristics of individuals with pulmonary tuberculosis (TB) in three districts of South India, 2015-2018(N=765)

Characteristic	Frequency (%)
Sputum Smear Grading at Diagnosis	
1+	241 (31.5)
2+	255 (33.3)
3+	269 (35.2)
Karnofsky Score at diagnosis	
50-60	218 (28.5)
>60	547 (71.5)
HIV Status	
Sero-positive	5 (0.6)
Sero-negative	760 (99.4)
Random Blood sugar	
<200mg/dl	531 (69.4)
≥200mg/dl	234 (30.6)
Any other Co-morbidity*	
Yes	154 (20.2)
No	611 (79.8)
Body Mass Index	
< 18.5	470 (61.4)
18.5 – 22.9	221 (28.9)
23 – 24.9	42 (5.5)
25 and above	29 (3.8)
Not recorded	3 (0.4)
Alcohol Use †	
Ever	446 (58.3)
Never	319 (41.7)
Tobacco Use ‡	
Former	140 (18.3)
Current	231 (30.2)

Never	394 (51.5)

*Other co-morbidities such as asthma, hepatitis, renal disease, cancer and breathing difficulty were reported by the participants

† Alcohol use- Alcohol use was measured for the past one year

‡Tobacco use- current or prior habitual use of both smoke and smokeless form of tobacco

Table 3: Components of household food insecurity among households of pulmonary tuberculosis (TB) patients in three districts of South India, 2015-2018. (N=765)

Occurrence Questions	Occurrence*			
	No	Rarely	Sometimes	Often
I. Worry or anxiety about food				
1.worry that the household would not have enough food	648 (84.7)	52 (6.8)	62 (8.1)	3 (0.4)
II. Insufficient Quality of Food				
2. Any household member not able to eat the kinds of foods preferred because of lack of resources	636 (83.1)	67 (8.8)	60 (7.8)	2 (0.3)
3. Eat a limited variety of foods due to a lack of resources	680 (88.9)	40 (5.2)	45 (5.9)	0 (0.0)
4. Any household member have to eat some foods that really did not want to eat because of a lack of resources to obtain other types of food	611 (79.9)	53 (6.9)	91 (11.9)	10 (1.3)
III. Insufficient Quantity of Food				
5. Any household member have to eat a smaller meal than needed because there was not enough food	593 (77.5)	73 (9.5)	97 (12.7)	2 (0.3)
6. Eat fewer meals in a day because there was not enough food	601 (78.6)	89 (11.6)	73 (9.5)	2 (0.3)
7.There ever no food to eat of any kind in your household because of lack of resources to get food	625 (81.7)	73 (9.5)	60 (7.8)	7 (0.9)
8. Any household member go to sleep at night hungry because there was not enough food	643 (84.1)	70 (9.2)	51 (6.7)	1 (0.1)

9. Any household member go a whole day and night without eating anything because there was not enough food	631 (82.5)	73 (9.5)	57 (7.5)	4 (0.5)

*0=No, 1 = Rarely (once or twice in the past four weeks), 2 = Sometimes (three to ten times in the past four weeks), 3 = Often (more than ten times in the past four weeks)

Table 4: Association of socio-demographic, morbidity, and behavioural characteristics with household food insecurity among individuals with pulmonary TB in Puducherry, N= 765

Characteristics	Total	Food insecurity*	Unadjusted PR† (95% CI) ‡	Adjusted PR†, § (95%CI) ‡
Total	765	261(34.1)	-	-
Age (in years)				
15-29	130	48 (36.9)	1.4 (0.9-2.0)	1.2 (0.7-2.2)
30-44	229	86 (37.6)	1.4 (1.0-1.9)	1.4 (0.9-2.2)
45-59	292	96 (39.9)	1.2 (0.9-1.7)	1.2 (0.8-1.8)
60 and above	114	31 (27.2)	1.0	Ref
Gender				
Male	611	203 (33.2)	1.0	Ref
Female	154	58 (37.7)	1.1 (0.91.4)	1.2 (0.8-1.8)
Marital Status				
Never Married	132	42 (31.8)	0.9 (0.7-1.2)	-
Married/Living together	567	196 (34.6)	1.0	-
Separated/divorced/ widowed	66	23 (34.9)	1.008 (0.7-1.4)	-
Education (years of schooling)				
No formal Education	131	40 (30.5)	1.0	-
1-5	160	54 (33.7)	1.10 (0.8-1.5)	-
6-10	317	114 (34.0)	1.2 (0.9-1.6)	-
>10	157	53 (33.8)	1.1 (0.8-1.6)	-
Employment				
Employed	588	206 (35.0)	1.1 (0.9-1.4)	1.4 (1.0-2.0)
Unemployed	177	55 (31.7)	1.0	Ref
Household Income per month (in INR)				
< 3000	80	41 (51.3)	1.9 (1.3-2.4)	2.0 (1.3- 3.0)
3000-5000	296	107 (36.2)	1.3 (1.0-1.6)	1.3 (0.9-1.7)

5001-10000	279	80 (28.7)	1.0	Ref
>10000	94	24 (25.5)	0.9 (0.6-1.3)	0.9 (0.6-1.6)
Didn't answer	16	9 (56.3)	2.0 (1.2-3.1)	2.2 (1.1-4.5)
Number of individuals in house				
≤3	604	198 (32.8)	1.0	Ref
>3	161	63 (39.1)	1.2 (0.9- 1.5)	1.3 (0.9-1.8)
Residence‖				
Urban	338	114 (33.7)	1.0	-
Rural	409	143 (34.0)	1.03 (0.8-1.3)	-
Number of earners in the household				
None	15	5 (33.3)	1.0	-
One	509	177 (34.8)	1.04 (0.5-2.2)	-
Two or more	241	79 (32.8)	0.9 (0.5-2.1)	-
Sputum Smear Grading at Diagnosis				
1+	241	68 (28.2)	1.0	Ref
2+	255	93 (36.5)	1.3 (1.0-1.7)	1.3 (0.9-1.7)
3+	269	100 (37.2)	1.3 (1.0-1.7)	0.4 (0.1-1.3)
Karnofsky Score at diagnosis				
50-60	218	97 (44.5)	1.5 (1.2-1.8)	1.5 (1.1-1.9)
>60	547	164 (30.0)	1.0	Ref
HIV Status				
Sero-positive	5	3 (60.0)	1.0	-
Sero-negative	760	258 (34.0)	0.6 (0.3-1.2)	-
Random Blood sugar				
<200mg/dl	531	197 (37.1)	1.4 (1.1-1.7)	1.1 (0.8-1.6)
≥200mg/dl	234	64 (27.4)	1.0	Ref
Any other Co-morbidity				
Yes	154	53 (34.4)	1.01 (0.8-1.3)	-
No	611	208 (34.0)	1.0	-
Body Mass Index‖				

< 18.5	470	177 (37.7)	1.2 (1.0-1.5)	1.06 (0.8-1.4)
18.5 – 22.9	221	68 (30.8)	1.0	Ref
23 – 24.9	42	12 (28.6)	0.9 (0.6-1.6))	0.9 (0.5-1.9)
25 and above	29	3 (10.3)	0.3 (0.1-1.0)	0.4 (0.1-1.3)
Alcohol Use				
Ever	446	160 (35.9)	1.1 (0.9-1.4)	-
Never	319	101 (31.7)	1.0	-
Tobacco Use				
Former	140	51 (36.4)	1.2 (0.9-1.5)	-
Current	231	86 (37.2)	1.2 (0.9-1.5)	-
Never	394	124 (31.5)	1.0	-

*Level of Food insecurity was assessed using the Household Food Insecurity Assessment Scale (HFIAS) for Measurement of Food Access-FANTAIII

†PR- Prevalence ratio

‡ CI-Confidence Interval

§ Adjusted for characteristics with p-value<0.2 in the univariate model

‖ Residence - Data is missing for 18 participants, Body Mass Index- Data is missing for 3 participants

ANNEXURE 1

Household Food Insecurity Access Scale (HFIAS) Measurement Tool

Occurrence Questions	Occurrence[1]			
	No	Rarely	Sometimes	Often
I. Worry or anxiety about food				
1.worry that the household would not have enough food				
II. Insufficient Quality of Food				
2. Any household member not able to eat the kinds of foods preferred because of lack of resources				
3. Eat a limited variety of foods due to a lack of resources				
4. Any household member have to eat some foods that really did not want to eat because of a lack of resources to obtain other types of food				
III. Insufficient Quantity of Food				
5. Any household member have to eat a smaller meal than needed because there was not enough food				
6. Eat fewer meals in a day because there was not enough food				
7.There ever no food to eat of any kind in your household because of lack of resources to get food				
8. Any household member go to sleep at night hungry because there was not enough food				

9. Any household member go a whole day and night without eating anything because there was not enough food				

10=No, 1 = Rarely (once or twice in the past four weeks), 2 = Sometimes (three to ten times in the past four weeks), 3 = Often (more than ten times in the past four weeks)

HFIA category

- 1 = Food Secure
  - HFIA category = 1 if [(Q1a=0 or Q1a=1) and Q2-Q9=0]
- 2=Mildly Food Insecure Access
  - HFIA category = 2 if [(Q1a=2 or Q1a=3 or Q2a=1 or Q2a=2 or Q2a=3 or Q3a=1 or Q4a=1) and Q5-Q9=0]
- 3=Moderately Food Insecure Access
  - HFIA category = 3 if [(Q3a=2 or Q3a=3 or Q4a=2 or Q4a=3 or Q5a=1 or Q5a=2 or Q6a=1 or Q6a=2) and Q7-Q9=0]
- 4=Severely Food Insecure Access
  - HFIA category = 4 if [Q5a=3 or Q6a=3 or Q7a=1 or Q7a=2 or Q7a=3 or Q8a=1 or Q8a=2 or Q8a=3 or Q9a=1 or Q9a=2 or Q9a=3]

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Household food insecurity among pulmonary tuberculosis patients and its associated factors in south India: A cross-sectional analysis

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Household food insecurity among pulmonary tuberculosis patients and its associated factors in south India: A cross sectional analysis

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ABSTRACT

Objectives

Food insecurity is 'the limited or uncertain availability of nutritionally adequate, safe foods or inability to acquire foods in socially acceptable ways'. Majority of Tuberculosis (TB) cases of resource-poor settings experience food insecurity, which impacts treatment adherence and outcomes. We aimed to determine level of household food insecurity (HFI)and its associated factors in pulmonary tuberculosis (TB) patients.

Design

This is a cross sectional analysis of data from an ongoing cohort study.

Setting

National Tuberculosis Program (NTP) in three districts of south India.

Participants

All newly diagnosed pulmonary TB cases of the cohort enrolled from National Tuberculosis Program at the Designated Microscopy Centres (DMCs) and Primary Health Centres (PHCs) from October 2015 to October 2018.

Primary Outcome Measures

The proportion of baseline HFI assessed using a validated household food insecurity access scale was summarized as percentage with 95% confidence interval (CI). Possible association of socio-demographic, morbidity and behavioural characteristics with HFI was assessed using chi-squared test, unadjusted prevalence ratios with 95% CI were calculated. The characteristics with p value less than 0.2 in the univariate model were included in multivariable generalized linear model (binomial function, log link) to derive adjusted prevalence ratios (aPR) with 95% CI.

Result

Of total 765 patients, 261 had HFI and the proportion was 34.1% (95% CI 30.8-37.6%). Mild, moderate and severe food insecurity was found in 17 (2.2%), 67 (8.8%) and 177 (23.1%) TB cases respectively. TB patients who had monthly family income less than INR 3000 (aPR 2.0; 95% 1.3-3.0), Karnofsky score of 60 or less (aPR 1.5; 95% 1.1-1.9) and those who were employed (aPR 1.4; 95% 1.0-2.0) had higher proportion of HFI.

Conclusions

High level of food insecurity was seen in households of TB cases. Additional food or cash assistance for this subgroup might improve food insecurity and thereby nutritional status.

Key Words

Undernutrition, HFIA scale, Karnofsky score, food assistance, SORT IT

Article Summary

Strengths:

- Use of a validated tool for assessing household food insecurity which allows cross country comparisons.
- We used the data from a prospective cohort study which implemented quality assurance checks for data collection, entry and completeness that would have reduced missing data and data errors.
- Our study included patients identified in the public sector alone and food insecurity levels may be different in patients accessing TB care in the private sector.

Limitations:

- We did not study the sub group of previously treated TB patients in whom levels of food insecurity could be higher due to financial loss caused by repeated episodes of TB.
- The study participants were from selected three districts in south India, so generalizability of the findings is limited.

INTRODUCTION

Tuberculosis (TB) is the leading cause of death from a single infectious agent, ranking above HIV/AIDS and overall, the ninth leading cause of death worldwide. In 2017, there were an estimated 1.3 million TB deaths among HIV-negative people. India contributes roughly 25% of global incident TB cases and there were an estimated 421000 deaths annually due to TB in the year 2017. (1,2) In 2014, World Health

Organization (WHO) endorsed the "End TB strategy" in line with the Sustainable Development Goals (SDGs) developed by the United Nations (Goals 1, 2 and 3 deal with action on poverty, hunger and ensuring healthy lives and well-being of people) with a common aim to end the global TB epidemic.(1,3)

Food security is a state in which "all people at all times have both physical and economic access to sufficient food to meet their dietary needs for a productive and healthy life".(4) Catastrophic health expenditure is a common consequence of TB diagnosis, treatment and care which can lead to impoverishment and in turn food insecurity for TB patients. Food insecurity and under-nutrition share a bidirectional relationship with TB; both cause TB and could be consequences of TB. Undernutrition in patients with active TB can lead to worsening of disease, drug toxicity, drug malabsorption and death or relapse of disease. (5–7)

A recent national survey (2016) in Vietnam reported that 22% of households experienced food insecurity during TB treatment, this proportion being as high as 40% among the poorest wealth quintiles.(8) Food insecurity at the household level is common in India and is a strong risk factor for progression of latent infection to active TB in household contacts.(9) TB in India affects poor families and communities disproportionately, with a fourfold higher prevalence in those with a low standard of living index compared to those with a high standard of living index.(5) Food insecurity is also of greatest significance in households where levels of food insecurity and undernutrition are high at the time of diagnosis. Since food insecurity and under-nutrition can co-exist, patients with TB are unable to regain a normal weight, despite effective treatment.

WHO (2013) in its guidelines 'Nutritional care and support for patients with tuberculosis' recommends assessment of food insecurity among TB cases and addressing the same with suitable packages including food assistance.(3) Recently, Government of India has launched a cash assistance scheme for all TB cases to mitigate costs and improve nutritional status. (10) However, there may be households with more food insecurity that need more food assistance rather than equal assistance to all. In India, studies assessing household food insecurity among TB cases are limited. Therefore, we aimed to determine the level of food insecurity and its associated factors using secondary data from a cohort of pulmonary TB patients in south India.

METHODS

Study Design

This is a cross sectional analysis of data from a cohort study under RePORT India Consortium (Regional Prospective Observational Research for Tuberculosis). Details of the study design have been previously reported. (11–14)

National tuberculosis program (NTP)

The study covers Puducherry district of Union Territory of Puducherry (population~1.3 million) and two adjoining districts of Tamil Nadu i.e. Villupuram (population~3.5 million) and Cuddalore (population~2.6 million). Under the national program (NTP), TB diagnostic and treatment services are delivered through the designated microscopy centres (DMCs) and peripheral health institutions (PHIs) under Tuberculosis units (TUs) as nodal points for TB control activities at sub-district level. Sputum smear microscopy remains the central component of TB diagnosis. Under NTP, both diagnosis and treatment are provided free of cost to the TB patients. On diagnosis of TB, the patients are referred to the nearest PHI for initiation of treatment. Morbidity details (diabetes, HIV) and medication adherence, follow-up details and TB treatment outcomes of these patients are documented in individual TB treatment card.

RePORT International

Regional Prospective Observational Research in Tuberculosis (RePORT) International represents a consortium of regional cohorts (RePORT India, RePORT Brazil, RePORT South Africa, RePORT China, RePORT Philippines and RePORT Indonesia) that are linked through the implementation of a common protocol for data and specimen collection. Objectives and composition of RePORT International are described elsewhere.(15)

One of the five teams under RePORT India, Jawaharlal Institute of Postgraduate Medical Education & Research (JIPMER) Boston Medical Center and Rutgers

University has established a pulmonary TB cohort of adults and children ≥ 6 years and their household contacts to identify biomarkers for risk of TB treatment failure and risk of development of TB in household contacts. TB cases diagnosed under NTP in the three districts (Puducherry, Cuddalore and Villupuram) were enrolled in the cohort at the designated microscopy centres and public health centres since 2014. Only newly diagnosed smear and culture positive pulmonary TB cases were included. Details on data collection and procedures were previously reported (11-14).

Study population

For this analysis, we included all TB cases of the cohort enrolled from October 2015 to October 2018. Multi drug resistant and extremely drug resistant TB cases at diagnosis were excluded.

Study tool

Household Food Insecurity Access Scale (HFIAS)(4) was used to assess food insecurity in the households in the past 30 days. The scale consists of nine items grouped under three domains: 1) anxiety or uncertainty about the household food supply 2) Insufficient Quality and 3) Insufficient food intake and its physical consequences (4). The respondent is first asked an occurrence question, whether the condition in the question happened at all in the past four weeks (yes or no). If the respondent answers “yes” to an occurrence question, a frequency-of-occurrence question is asked to determine whether the condition happened rarely (once or twice), sometimes (three to ten times) or often (more than ten times) in the past four weeks. Each item is scored on a range of 0 to 3; zero for ‘no occurrence’ and three for ‘often’. The minimum and maximum score for a household are0 and27 respectively. The

scores were categorized into four levels of household food insecurity: food secure and mild, moderately and severely food insecure (4)-Annexure 1.

Alcohol Use Disorders Identification Test (AUDIT)-C questionnaire (a modified version of AUDIT) (16) was used to assess the alcohol use among participants.

Data extraction, analysis and statistics

Of total 1229 TB cases enrolled in the cohort, we extracted data for 765 cases excluding two childhood TB cases; the initial 462 cases enrolled were not assessed for household food insecurity and were excluded. Data were extracted from the RePORT India project database for JIPMER site in a de-identified manner and analysed using Stata 12.0 software. The proportion of household food insecurity was summarized as percentage with 95% confidence interval (CI). Possible association of socio-demographic, morbidity related and behavioural characteristics with household food insecurity was assessed using chi-squared test and unadjusted prevalence ratios with 95% CI were calculated. The characteristics with p value less than 0.2 in the univariate model were included in multivariable generalized linear model (binomial function and log link) to derive adjusted prevalence ratios(aPR) with 95% CI. The variables such as marital status, education, residence, number of earners in the household, HIV status, tobacco use, and alcohol use were not included for multivariate analysis.

Ethics Approval

Ethics approval was obtained from the Institutional Ethics Committee of JIPMER (Ref.No: JIP/IEC/2013/4/194) and Institute Review Board of Boston Medical Center (IRB No: H-32657/7-05-2017) for the cohort study. Written informed consent was obtained from all participants before enrolment. The study protocol for this secondary

analysis was reviewed and approved by Ethics Advisory Group of the International Union Against Tuberculosis and Lung Disease (99/18), Paris, France.

Data sharing document:

Technical appendix, statistical code, and data set will be available upon request from the Corresponding author.

Patient and Public Involvement

There was no patient or public involvement.

RESULTS

Of the 765 individuals included in analysis, the mean (standard deviation) age was 44 (14) years; 611 (80%) were males. Socio-demographic characteristics of TB cases are described in **Table-1**. Of total, 131 (17%) participants did not have any formal education, about 77% were employed and 11% had monthly family income less than INR 3000 (~USD 43). Behavioural and disease related characteristics are described in **Table-2**. More than half (58%) were alcohol users (in the previous year) and 30% were current tobacco users. Of total, 470 (61%) were underweight (body mass index <18.5 kg/m2) and five patients (0.6%) were HIV-infected. Karnofsky score was 60 or less (require assistance for routine activities) in 29% of patients.

Overall, 261 patients had household food insecurity and the proportion was 34.1% (95% CI 30.8-37.6%). Mild, moderate and severe food insecurity was found in 17 (2.2%), 67 (8.8%) and 177 (23.1%) TB cases respectively. Components of food insecurity are described in **Table-3**. Worry or anxiety about not having enough food was reported in 15% of TB households. In 21% of TB households, eating fewer meals in a day due to lack of enough food was reported.

Level of food insecurity in different sub groups is presented in **Table-4**. In adjusted analysis, TB cases who had monthly family income less than INR 3000 (aPR 2.0; 95% 1.3-3.0), Karnofsky score of 60 or less (aPR 1.5; 95% 1.1-1.9) and those who were employed (aPR 1.4; 95% 1.0-2.0) had higher proportion of household food insecurity.

DISCUSSION

Our study among newly diagnosed pulmonary TB patients in public sector in south India revealed that about one third of TB patients experienced household food insecurity; about one out of four patients experienced severe food insecurity at the time of diagnosis.Level of food insecurity was high in low income groups, employed and those who had severe illness.

Prevalence of food insecurity in the general population of India is also high ranging from 45.5% to 77.2%. (17,18) Hence, household food insecurity among TB patients is common as it can be both a cause and consequence of TB. The national level survey

from Vietnam (2016) reported 22% of TB patients experienced household food insecurity; lower levels of 6% were reported among TB patients in Sri Lanka. (8,19)

Food insecurity was twice as high in low income TB households (INR<3000) compared to their higher income counterparts. Catastrophic health expenditure, a consequence of TB diagnosis and treatment can lead to worsening of food insecurity in low income groups during the course of the disease.(5) These subgroups need to be provided additional assistance instead of 'equal for all' food or cash assistance benefits. Since income is usually underreported, identifying such target groups may not be an easy task.

Food insecurity at the household level is a strong risk factor for progression of latent infection to active TB in household contacts. (9,20) Since, food insecurity measures are applicable to all households, a wider approach of reducing food insecurity targeting all household contacts is needed.

In our study, about 60% of the TB patients were underweight. Undernutrition is both an important risk factor for, and a common consequence of TB. In food insecure households, undernutrition could be an intermediary step in the nutritional pathway of food insecurity leading to morbidity like TB. In India, undernutrition is highly prevalent in patients with TB and the dietary intake of calories is significantly lower (500-700 calories) than recommended. (21) As recommended by WHO, addressing undernutrition through nutritional counselling and support should be considered as part of the standard of care for people with TB. The recently launched "Nikshay Poshan Yojana", a direct benefit transfer scheme by the government of India is a welcome step towards addressing undernutrition. (22) Our study did not include severely ill patients (Karnofsky score<40) and previously treated TB patients in whom undernutrition rates

are expected to be high. This may partly explain why our study did not find an association between food insecurity and undernutrition, though previous studies have reported otherwise. (23–26) Also, we have assessed food insecurity at the level of household and body mass index assessed is that of the individual patients. May be the patient's nutrition is maintained at the expense of other family members, so he or she may have had normal BMI. In this study, we couldn't explore details on employment such as type of employment, which could be a risk factor for development of TB and could have influenced the income and thus the ability to purchase food items also.

Several studies support the notion that food insecurity negatively affects treatment adherence. Conditions of food insecurity (lack of adequate food, concern about daily food production) contribute to non-adherence to TB treatment as reported by qualitative studies. (27–29) Hence, identifying food insecurity at the time of diagnosis and linking the patients to food assistance or social security programs is needed. We plan to report the effect of food insecurity on adherence and TB treatment outcomes in a separate paper.

Strengths of the study include use of a validated tool (4) for assessing household food insecurity which allows cross country comparisons. We used the data from a prospective cohort study which implemented quality assurance checks for data collection and entry that would have reduced missing data and data errors. Our study included patients identified in the public sector alone and food insecurity levels may be different in patients accessing TB care in the private sector. Since, repeated episodes of TB may be a cause for financial loss leading to food insecurity, the levels could be higher in previously treated TB patients and we did not study this sub group. Being a cross sectional analysis, causal relationships of factors with food insecurity

cannot be inferred. The study participants were from selected three districts in south India, so generalisability of the findings is limited.

CONCLUSION

To conclude, household food insecurity was experienced by one in three TB patients and this was twice higher in low income groups. Additional food or cash assistance to food insecure TB patients and household contacts will improve the food insecurity and undernutrition.

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COMPETING INTERESTS

The authors have declared that no competing interests exist.

CONTRIBUTION OF AUTHORS

RA: Principal Investigator (PI), conception/ design of the protocol, data capture, development of data capture tool, data analysis / interpretation, drafting / critically reviewing the paper, giving approval for the final version to be published

SS: Acquisition of data, conception/ design of the protocol, revision of manuscript, critically reviewing the paper, giving approval for the final version to be published

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Table 1: Socio-demographic characteristics of individuals with pulmonary tuberculosis (TB) in three districts of South India, 2015-2018. (N=765)

Characteristics	Frequency (%)
Age (in years)	
15-29	130 (17.0)
30-44	229 (29.9)
45-59	292 (38.2)

60 and above	114 (14.9)
Gender	
Male	611 (79.9)
Female	154 (20.1)
Marital Status	
Never Married	132 (17.3)
Married/Living together	567 (74.1)
Separated/divorced/ widowed	66 (8.6)
Education (years of schooling)	
No formal Education	131 (17.1)
1-5	160 (20.9)
6-10	317 (41.4)
>10	157 (20.5)
Employment	
Employed	588 (76.9)
Unemployed	177 (23.1)
Household Income per month (in INR)	
< 3000	80 (10.5)
3000-5000	296 (38.7)
5001-10000	279 (36.5)
>10000	94 (12.3)
Didn't answer	16 (2.0)
Number of individuals in house	
≤3	604 (78.9)
>3	161 (21.1)
Residence*	
Urban	338 (44.2)
Rural	409 (53.4)
Not recorded	18 (2.4)
Number of earners in the household	
None	15 (1.9)
One	509 (66.5)

Two or more	241 (31.6)
Religion	
Hindu	677 (88.5)
Christianity	54 (7.1)
Muslim	32 (4.2)
Others	2 (0.3)

Table 2: Morbidity and behavioural characteristics of individuals with pulmonary tuberculosis (TB) in three districts of South India, 2015-2018(N=765)

Characteristic	Frequency (%)
Sputum Smear Grading at Diagnosis	
1+	241 (31.5)
2+	255 (33.3)
3+	269 (35.2)

Karnofsky Score at diagnosis	
50-60	218 (28.5)
>60	547 (71.5)
HIV Status	
Sero-positive	5 (0.6)
Sero-negative	760 (99.4)
Random Blood sugar	
<200mg/dl	531 (69.4)
≥200mg/dl	234 (30.6)
Any other Co-morbidity*	
Yes	154 (20.2)
No	611 (79.8)
Body Mass Index	
< 18.5	470 (61.4)
18.5 – 22.9	221 (28.9)
23 – 24.9	42 (5.5)
25 and above	29 (3.8)
Not recorded	3 (0.4)
Alcohol Use †	
Ever	446 (58.3)
Never	319 (41.7)
Tobacco Use ‡	
Former	140 (18.3)
Current	231 (30.2)
Never	394 (51.5)

*Other co-morbidities such as asthma, hepatitis, renal disease, cancer and breathing difficulty were reported by the participants

† Alcohol use- Alcohol use was measured for the past one year

‡Tobacco use- current or prior habitual use of both smoke and smokeless form of tobacco

Table 3: Components of household food insecurity among households of pulmonary tuberculosis (TB) patients in three districts of South India, 2015-2018. (N=765)

Occurrence Questions	Occurrence*			
	No	Rarely	Sometimes	Often
I. Worry or anxiety about food				

1.worry that the household would not have enough food	648 (84.7)	52 (6.8)	62 (8.1)	3 (0.4)
II. Insufficient Quality of Food				
2. Any household member not able to eat the kinds of foods preferred because of lack of resources	636 (83.1)	67 (8.8)	60 (7.8)	2 (0.3)
3. Eat a limited variety of foods due to a lack of resources	680 (88.9)	40 (5.2)	45 (5.9)	0 (0.0)
4. Any household member have to eat some foods that really did not want to eat because of a lack of resources to obtain other types of food	611 (79.9)	53 (6.9)	91 (11.9)	10 (1.3)
III. Insufficient Quantity of Food				
5. Any household member have to eat a smaller meal than needed because there was not enough food	593 (77.5)	73 (9.5)	97 (12.7)	2 (0.3)
6. Eat fewer meals in a day because there was not enough food	601 (78.6)	89 (11.6)	73 (9.5)	2 (0.3)
7.There ever no food to eat of any kind in your household because of lack of resources to get food	625 (81.7)	73 (9.5)	60 (7.8)	7 (0.9)
8. Any household member go to sleep at night hungry because there was not enough food	643 (84.1)	70 (9.2)	51 (6.7)	1 (0.1)
9. Any household member go a whole day and night without eating anything because there was not enough food	631 (82.5)	73 (9.5)	57 (7.5)	4 (0.5)

*0=No, 1 = Rarely (once or twice in the past four weeks), 2 = Sometimes (three to ten times in the past four weeks), 3 = Often (more than ten times in the past four weeks)

Table 4: Association of socio-demographic, morbidity, and behavioural characteristics with household food insecurity among individuals with pulmonary TB in Puducherry, N= 765

Characteristics	Total	Food insecurity*	Unadjusted PR† (95% CI) ‡	Adjusted PR†, § (95%CI) ‡
Total	765	261(34.1)	-	-
Age (in years)				

15-29	130	48 (36.9)	1.4 (0.9-2.0)	1.2 (0.7-2.2)
30-44	229	86 (37.6)	1.4 (1.0-1.9)	1.4 (0.9-2.2)
45-59	292	96 (39.9)	1.2 (0.9-1.7)	1.2 (0.8-1.8)
60 and above	114	31 (27.2)	1.0	Ref
Gender				
Male	611	203 (33.2)	1.0	Ref
Female	154	58 (37.7)	1.1 (0.91.4)	1.2 (0.8-1.8)
Marital Status				
Never Married	132	42 (31.8)	0.9 (0.7-1.2)	-
Married/Living together	567	196 (34.6)	1.0	-
Separated/divorced/ widowed	66	23 (34.9)	1.008 (0.7-1.4)	-
Education (years of schooling)				
No formal Education	131	40 (30.5)	1.0	-
1-5	160	54 (33.7)	1.10 (0.8-1.5)	-
6-10	317	114 (34.0)	1.2 (0.9-1.6)	-
>10	157	53 (33.8)	1.1 (0.8-1.6)	-
Employment				
Employed	588	206 (35.0)	1.1 (0.9-1.4)	1.4 (1.0-2.0)
Unemployed	177	55 (31.7)	1.0	Ref
Household Income per month (in INR)				
< 3000	80	41 (51.3)	1.9 (1.3-2.4)	2.0 (1.3- 3.0)
3000-5000	296	107 (36.2)	1.3 (1.0-1.6)	1.3 (0.9-1.7)
5001-10000	279	80 (28.7)	1.0	Ref
>10000	94	24 (25.5)	0.9 (0.6-1.3)	0.9 (0.6-1.6)
Didn't answer	16	9 (56.3)	2.0 (1.2-3.1)	2.2 (1.1-4.5)
Number of individuals in house				
≤3	604	198 (32.8)	1.0	Ref
>3	161	63 (39.1)	1.2 (0.9- 1.5)	1.3 (0.9-1.8)
Residence‖				
Urban	338	114 (33.7)	1.0	-
Rural	409	143 (34.0)	1.03 (0.8-1.3)	-

Number of earners in the household				
None	15	5 (33.3)	1.0	-
One	509	177 (34.8)	1.04 (0.5-2.2)	-
Two or more	241	79 (32.8)	0.9 (0.5-2.1)	-
Sputum Smear Grading at Diagnosis				
1+	241	68 (28.2)	1.0	Ref
2+	255	93 (36.5)	1.3 (1.0-1.7)	1.3 (0.9-1.7)
3+	269	100 (37.2)	1.3 (1.0-1.7)	0.4 (0.1-1.3)
Karnofsky Score at diagnosis				
50-60	218	97 (44.5)	1.5 (1.2-1.8)	1.5 (1.1-1.9)
>60	547	164 (30.0)	1.0	Ref
HIV Status				
Sero-positive	5	3 (60.0)	1.0	-
Sero-negative	760	258 (34.0)	0.6 (0.3-1.2)	-
Random Blood sugar				
<200mg/dl	531	197 (37.1)	1.4 (1.1-1.7)	1.1 (0.8-1.6)
≥200mg/dl	234	64 (27.4)	1.0	Ref
Any other Co-morbidity				
Yes	154	53 (34.4)	1.01 (0.8-1.3)	-
No	611	208 (34.0)	1.0	-
Body Mass Index‖				
< 18.5	470	177 (37.7)	1.2 (1.0-1.5)	1.06 (0.8-1.4)
18.5 – 22.9	221	68 (30.8)	1.0	Ref
23 – 24.9	42	12 (28.6)	0.9 (0.6-1.6))	0.9 (0.5-1.9)
25 and above	29	3 (10.3)	0.3 (0.1-1.0)	0.4 (0.1-1.3)
Alcohol Use				
Ever	446	160 (35.9)	1.1 (0.9-1.4)	-
Never	319	101 (31.7)	1.0	-
Tobacco Use				
Former	140	51 (36.4)	1.2 (0.9-1.5)	-

Current	231	86 (37.2)	1.2 (0.9-1.5)	-
Never	394	124 (31.5)	1.0	-

*Level of Food insecurity was assessed using the Household Food Insecurity Assessment Scale (HFIAS) for Measurement of Food Access-FANTAIII

†PR- Prevalence ratio

‡ CI-Confidence Interval

§ Adjusted for characteristics with p-value<0.2 in the univariate model

‖ Residence - Data is missing for 18 participants, Body Mass Index- Data is missing for 3 participants

ANNEXURE 1

Household Food Insecurity Access Scale (HFIAS) Measurement Tool

Occurrence Questions	Occurrence[1]			
	No	Rarely	Sometimes	Often
I. Worry or anxiety about food				
1.worry that the household would not have enough food				
II. Insufficient Quality of Food				
2. Any household member not able to eat the kinds of foods preferred because of lack of resources				
3. Eat a limited variety of foods due to a lack of resources				
4. Any household member have to eat some foods that really did not want to eat because of a lack of resources to obtain other types of food				
III. Insufficient Quantity of Food				
5. Any household member have to eat a smaller meal than needed because there was not enough food				
6. Eat fewer meals in a day because there was not enough food				
7.There ever no food to eat of any kind in your household because of lack of resources to get food				
8. Any household member go to sleep at night hungry because there was not enough food				

9. Any household member go a whole day and night without eating anything because there was not enough food				

10=No, 1 = Rarely (once or twice in the past four weeks), 2 = Sometimes (three to ten times in the past four weeks), 3 = Often (more than ten times in the past four weeks)

HFIA category

- 1 = Food Secure
  - HFIA category = 1 if [(Q1a=0 or Q1a=1) and Q2-Q9=0]
- 2=Mildly Food Insecure Access
  - HFIA category = 2 if [(Q1a=2 or Q1a=3 or Q2a=1 or Q2a=2 or Q2a=3 or Q3a=1 or Q4a=1) and Q5-Q9=0]
- 3=Moderately Food Insecure Access
  - HFIA category = 3 if [(Q3a=2 or Q3a=3 or Q4a=2 or Q4a=3 or Q5a=1 or Q5a=2 or Q6a=1 or Q6a=2) and Q7-Q9=0]
- 4=Severely Food Insecure Access
  - HFIA category = 4 if [Q5a=3 or Q6a=3 or Q7a=1 or Q7a=2 or Q7a=3 or Q8a=1 or Q8a=2 or Q8a=3 or Q9a=1 or Q9a=2 or Q9a=3]

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Household Food insecurity in TB patients

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ABSTRACT

Objectives

Food insecurity is 'the limited or uncertain availability of nutritionally adequate, safe foods or inability to acquire foods in socially acceptable ways'. Majority of Tuberculosis (TB) cases of resource-poor settings experience food insecurity, which impacts treatment adherence and outcomes. We aimed to determine level of household food insecurity (HFI)and its associated factors in pulmonary tuberculosis (TB) patients.

Design

This is a cross sectional analysis of data from an ongoing cohort study.

Setting

National Tuberculosis Program (NTP) in three districts of south India.

Participants

All newly diagnosed pulmonary TB cases of the cohort enrolled from National Tuberculosis Program at the Designated Microscopy Centres (DMCs) and Primary Health Centres (PHCs) from October 2015 to October 2018.

Primary Outcome Measures

The proportion of baseline HFI assessed using a validated household food insecurity access scale was summarized as percentage with 95% confidence interval (CI). Possible association of socio-demographic, morbidity and behavioural characteristics with HFI was assessed using chi-squared test, unadjusted prevalence ratios with 95% CI were calculated. The characteristics with p value less than 0.2 in the univariate model were included in multivariable generalized linear model (binomial function, log link) to derive adjusted prevalence ratios (aPR) with 95% CI.

Result

Of total 765 patients, 261 had HFI and the proportion was 34.1% (95% CI 30.8-37.6%). Mild, moderate and severe food insecurity was found in 17 (2.2%), 67 (8.8%) and 177 (23.1%) TB cases respectively. TB patients who had monthly family income less than INR 3000 (aPR 2.0; 95% 1.3-3.0), Karnofsky score of 60 or less (aPR 1.5; 95% 1.1-1.9) and those who were employed (aPR 1.4; 95% 1.0-2.0) were independently associated with HFI.

Conclusions

High level of food insecurity was seen in households of TB cases. Additional food or cash assistance for this subgroup might improve food insecurity and thereby nutritional status.

Key Words

Undernutrition, HFIA scale, Karnofsky score, food assistance, SORT IT

Article Summary

Strengths:

- Use of a validated tool for assessing household food insecurity which allows cross country comparisons.
- We used the data from a prospective cohort study which implemented quality assurance checks for data collection, entry and completeness that would have reduced missing data and data errors.

Limitations:

- We did not study the sub group of previously treated TB patients in whom levels of food insecurity could be higher due to financial loss caused by repeated episodes of TB.
- The study participants were from selected three districts in south India, so generalizability of the findings is limited.
- The model developed for assessing the factors associated with HFI was deficient due to small sample size and unavailability of a few important confounding variables

INTRODUCTION

Tuberculosis (TB) is the leading cause of death from a single infectious agent, ranking above HIV/AIDS and overall, the ninth leading cause of death worldwide. In 2017, there were an estimated 1.3 million TB deaths among HIV-negative people. India contributes roughly 25% of global incident TB cases and there were an estimated 421000 deaths annually due to TB in the year 2017. (1,2) In 2014, World Health Organization (WHO) endorsed the "End TB strategy" in line with the Sustainable Development Goals (SDGs) developed by the United Nations (Goals 1, 2 and 3 deal with action on poverty, hunger and ensuring healthy lives and well-being of people) with a common aim to end the global TB epidemic.(1,3)

Food security is a state in which "all people at all times have both physical and economic access to sufficient food to meet their dietary needs for a productive and healthy life".(4) Catastrophic health expenditure is a common consequence of TB diagnosis, treatment and care which can lead to impoverishment and in turn food insecurity for TB patients. Food insecurity and under-nutrition share a bidirectional relationship with TB; both cause TB and could be consequences of TB. Undernutrition in patients with active TB can lead to worsening of disease, drug toxicity, drug malabsorption and death or relapse of disease. (5–7)

A recent national survey (2016) in Vietnam reported that 22% of households experienced food insecurity during TB treatment, this proportion being as high as 40% among the poorest wealth quintiles.(8) Food insecurity at the household level is common in India and is a strong risk factor for progression of latent infection to active TB in household contacts.(9) TB in India affects poor families and communities disproportionately, with a fourfold higher prevalence in those with a low standard of

living index compared to those with a high standard of living index.(5) Food insecurity is also of greatest significance in households where levels of food insecurity and undernutrition are high at the time of diagnosis. Since food insecurity and under-nutrition can co-exist, patients with TB are unable to regain a normal weight, despite effective treatment.

WHO (2013) in its guidelines 'Nutritional care and support for patients with tuberculosis' recommends assessment of food insecurity among TB cases and addressing the same with suitable packages including food assistance.(3) Recently, Government of India has launched a cash assistance scheme for all TB cases to mitigate costs and improve nutritional status. (10) However, there may be households with more food insecurity that need more food assistance rather than equal assistance to all. In India, studies assessing household food insecurity among TB cases are limited. Therefore, we aimed to determine the level of food insecurity and its associated factors using secondary data from a cohort of pulmonary TB patients in south India.

METHODS

Study Design

This is a cross sectional analysis of data from a cohort study under RePORT India Consortium (Regional Prospective Observational Research for Tuberculosis). Details of the study design have been previously reported. (11–14)

National tuberculosis program (NTP)

The study covers Puducherry district of Union Territory of Puducherry (population~1.3 million) and two adjoining districts of Tamil Nadu i.e. Villupuram (population~3.5 million) and Cuddalore (population~2.6 million). Under the national program (NTP), TB diagnostic and treatment services are delivered through the designated microscopy centres (DMCs) and peripheral health institutions (PHIs) under Tuberculosis units (TUs) as nodal points for TB control activities at sub-district level. Sputum smear microscopy remains the central component of TB diagnosis. Under NTP, both diagnosis and treatment are provided free of cost to the TB patients. On diagnosis of TB, the patients are referred to the nearest PHI for initiation of treatment. Morbidity details (diabetes, HIV) and medication adherence, follow-up details and TB treatment outcomes of these patients are documented in individual TB treatment card.

RePORT International

Regional Prospective Observational Research in Tuberculosis (RePORT) International represents a consortium of regional cohorts (RePORT India, RePORT Brazil, RePORT South Africa, RePORT China, RePORT Philippines and RePORT Indonesia) that are linked through the implementation of a common protocol for data and specimen collection. Objectives and composition of RePORT International are described elsewhere.(15)

One of the five teams under RePORT India, Jawaharlal Institute of Postgraduate Medical Education & Research (JIPMER) Boston Medical Center and Rutgers University has established a pulmonary TB cohort of adults and children ≥ 6 years and their household contacts to identify biomarkers for risk of TB treatment failure and risk of development of TB in household contacts. TB cases diagnosed under NTP in the three districts (Puducherry, Cuddalore and Villupuram) were enrolled in the cohort at the designated microscopy centres and public health centres since 2014. Only newly diagnosed smear and culture positive pulmonary TB cases were included. Details on data collection and procedures were previously reported (11-14).

Study population

For this analysis, we included all TB cases of the cohort enrolled from October 2015 to October 2018. Multi drug resistant and extremely drug resistant TB cases at diagnosis were excluded.

Study tool

Household Food Insecurity Access Scale (HFIAS)(4) was used to assess food insecurity in the households in the past 30 days. The scale consists of nine items grouped under three domains: 1) anxiety or uncertainty about the household food supply 2) Insufficient Quality and 3) Insufficient food intake and its physical consequences (4). The respondent is first asked an occurrence question, whether the condition in the question happened at all in the past four weeks (yes or no). If the respondent answers “yes” to an occurrence question, a frequency-of-occurrence question is asked to determine whether the condition happened rarely (once or twice), sometimes (three to ten times) or often (more than ten times) in the past four weeks.

Each item is scored on a range of 0 to 3; zero for 'no occurrence' and three for 'often'. The minimum and maximum score for a household are0 and27 respectively. The scores were categorized into four levels of household food insecurity: food secure and mild, moderately and severely food insecure (4)-Annexure 1.

Alcohol Use Disorders Identification Test (AUDIT)-C questionnaire (a modified version of AUDIT) (16) was used to assess the alcohol use among participants.

Data extraction, analysis and statistics

Of total 1229 TB cases enrolled in the cohort, we extracted data for 765 cases excluding two childhood TB cases; the initial 462 cases enrolled were not assessed for household food insecurity because of not having the HFAI scale in the study proforma during initial phase of the project. The HFAI scale was introduced in the revised study proforma after the 462 patients were already enrolled into the project. However, the 462 patients excluded had no difference in the baseline socio-demographic and clinical characteristics compared with those included in the study.

Data were extracted from the RePORT India project database for JIPMER site in a de-identified manner and analysed using Stata 12.0 software. The proportion of household food insecurity was summarized as percentage with 95% confidence interval (CI). Possible association of socio-demographic, morbidity related and behavioural characteristics with household food insecurity was assessed using chi-squared test and unadjusted prevalence ratios with 95% CI were calculated. The characteristics with p value less than 0.2 in the univariate model were included in multivariable generalized linear model (binomial function and log link) to derive adjusted prevalence ratios(aPR) with 95% CI. The variables such as marital status, education, residence, number of earners in the household, HIV status, tobacco use, and alcohol use were not included for multivariate analysis.

Ethics Approval

Ethics approval was obtained from the Institutional Ethics Committee of JIPMER (Ref.No: JIP/IEC/2013/4/194) and Institute Review Board of Boston Medical Center (IRB No: H-32657/7-05-2017) for the cohort study. Written informed consent was obtained from all participants before enrolment. The study protocol for this secondary analysis was reviewed and approved by Ethics Advisory Group of the International Union Against Tuberculosis and Lung Disease (99/18), Paris, France.

Data sharing document:

Technical appendix, statistical code, and data set will be available upon request from the Corresponding author.

Patient and Public Involvement

There was no patient or public involvement.

RESULTS

Of the 765 individuals included in analysis, the mean (standard deviation) age was 44 (14) years; 611 (80%) were males. Socio-demographic characteristics of TB cases are described in **Table-1**. Of total, 131 (17%) participants did not have any formal education, about 77% were employed and 11% had monthly family income less than INR 3000 (~USD 43). Behavioural and disease related characteristics are described in **Table-2**. More than half (58%) were alcohol users (in the previous year) and 30% were current tobacco users. Of total, 470 (61%) were underweight (body mass index <18.5 kg/m2) and five patients (0.6%) were HIV-infected. Karnofsky score was 60 or less (require assistance for routine activities) in 29% of patients.

Overall, 261 patients had household food insecurity and the proportion was 34.1% (95% CI 30.8-37.6%). Mild, moderate and severe food insecurity was found in 17 (2.2%), 67 (8.8%) and 177 (23.1%) TB cases respectively. Components of food insecurity are described in **Table-3**. Worry or anxiety about not having enough food was reported in 15% of TB households. In 21% of TB households, eating fewer meals in a day due to lack of enough food was reported.

Level of food insecurity in different sub groups is presented in **Table-4**. In adjusted analysis, TB cases who had monthly family income less than INR 3000 (aPR 2.0; 95% 1.3-3.0), Karnofsky score of 60 or less (aPR 1.5; 95% 1.1-1.9) and those who were employed (aPR 1.4; 95% 1.0-2.0) had higher proportion of household food insecurity.

DISCUSSION

Our study among newly diagnosed pulmonary TB patients in public sector in south India revealed that about one third of TB patients experienced household food insecurity; about one out of four patients experienced severe food insecurity at the time of diagnosis. Level of food insecurity was high in low income groups, employed and those who had severe illness.

Prevalence of food insecurity in the general population of India is also high ranging from 45.5% to 77.2%. (17,18) Hence, household food insecurity among TB patients is common as it can be both a cause and consequence of TB. The national level survey from Vietnam (2016) reported 22% of TB patients experienced household food insecurity; lower levels of 6% were reported among TB patients in Sri Lanka. (8,19)

Food insecurity was twice as high in low income TB households (INR<3000) compared to their higher income counterparts. Catastrophic health expenditure, a consequence of TB diagnosis and treatment can lead to worsening of food insecurity in low income groups during the course of the disease.(5) These subgroups need to be provided additional assistance instead of 'equal for all' food or cash assistance benefits. Since income is usually underreported, identifying such target groups may not be an easy task.

Food insecurity at the household level is a strong risk factor for progression of latent infection to active TB in household contacts. (9,20) Since, food insecurity measures are applicable to all households, a wider approach of reducing food insecurity targeting all household contacts is needed.

In our study, about 60% of the TB patients were underweight. Undernutrition is both an important risk factor for, and a common consequence of TB. In food insecure

households, undernutrition could be an intermediary step in the nutritional pathway of food insecurity leading to morbidity like TB. In India, undernutrition is highly prevalent in patients with TB and the dietary intake of calories is significantly lower (500-700 calories) than recommended. (21) As recommended by WHO, addressing undernutrition through nutritional counselling and support should be considered as part of the standard of care for people with TB. The recently launched "Nikshay Poshan Yojana", a direct benefit transfer scheme by the government of India is a welcome step towards addressing undernutrition. (22) Our study did not include severely ill patients (Karnofsky score<40) and previously treated TB patients in whom undernutrition rates are expected to be high. This may partly explain why our study did not find an association between food insecurity and undernutrition, though previous studies have reported otherwise. (23–26) Also, we have assessed food insecurity at the level of household and body mass index assessed is that of the individual patients. May be the patient's nutrition is maintained at the expense of other family members, so he or she may have had normal BMI. However, the temporality of the BMI, HFI and weight loss could not be established due to cross-sectional nature of this study and we also failed to account for sequence of these events during analysis. Thus, we fail to strongly comment on the causal pathways of association between HFI, BMI and weight loss. Also, we couldn't explore details on employment such as type of employment, which could be a risk factor for development of TB and could have influenced the income and thus the ability to purchase food items also.

Several studies support the notion that food insecurity negatively affects treatment adherence. Conditions of food insecurity (lack of adequate food, concern about daily food production) contribute to non-adherence to TB treatment as reported by qualitative studies. (27–29) Hence, identifying food insecurity at the time of diagnosis

and linking the patients to food assistance or social security programs is needed. We plan to report the effect of food insecurity on adherence and TB treatment outcomes in a separate paper.

Strengths of the study include use of a validated tool (4) for assessing household food insecurity which allows cross country comparisons. We used the data from a prospective cohort study which implemented quality assurance checks for data collection and entry that would have reduced missing data and data errors. There were a few limitations in the study. Our study included patients identified in the public sector alone and food insecurity levels may be different in patients accessing TB care in the private sector. Since, repeated episodes of TB may be a cause for financial loss leading to food insecurity, the levels could be higher in previously treated TB patients and we did not study this sub group. The study participants were from selected three districts in south India, so generalisability of the findings is limited. Being a cross sectional analysis, causal relationships of factors with food insecurity cannot be inferred. The model we constructed for exploring factors associated with HFI was deficient as a few important confounding variables were included and also, the small sample size (power) was less to perform rational statistical analyses. Thus, the factors associated with the HFI needs to be interpreted in caution considering this major limitation in multivariate analysis.

CONCLUSION

To conclude, household food insecurity was experienced by one in three TB patients and this was twice higher in low income groups. Additional food or cash assistance to

food insecure TB patients and household contacts will improve the food insecurity and undernutrition.

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COMPETING INTERESTS

The authors have declared that no competing interests exist.

CONTRIBUTION OF AUTHORS

RA: Principal Investigator (PI), conception/ design of the protocol, data capture, development of data capture tool, data analysis / interpretation, drafting / critically reviewing the paper, giving approval for the final version to be published

SS: Acquisition of data, conception/ design of the protocol, revision of manuscript, critically reviewing the paper, giving approval for the final version to be published

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Table 1: Socio-demographic characteristics of individuals with pulmonary tuberculosis (TB) in three districts of South India, 2015-2018. (N=765)

Characteristics	Frequency (%)
Age (in years)	
15-29	130 (17.0)
30-44	229 (29.9)
45-59	292 (38.2)
60 and above	114 (14.9)
Gender	
Male	611 (79.9)
Female	154 (20.1)
Marital Status	
Never Married	132 (17.3)
Married/Living together	567 (74.1)
Separated/divorced/ widowed	66 (8.6)
Education (years of schooling)	
No formal Education	131 (17.1)
1-5	160 (20.9)
6-10	317 (41.4)
>10	157 (20.5)
Employment	
Employed	588 (76.9)
Unemployed	177 (23.1)

Household Income per month (in INR)	
< 3000	80 (10.5)
3000-5000	296 (38.7)
5001-10000	279 (36.5)
>10000	94 (12.3)
Didn't answer	16 (2.0)
Number of individuals in house	
≤3	604 (78.9)
>3	161 (21.1)
Residence*	
Urban	338 (44.2)
Rural	409 (53.4)
Not recorded	18 (2.4)
Number of earners in the household	
None	15 (1.9)
One	509 (66.5)
Two or more	241 (31.6)
Religion	
Hindu	677 (88.5)
Christianity	54 (7.1)
Muslim	32 (4.2)
Others	2 (0.3)

Table 2: Morbidity and behavioural characteristics of individuals with pulmonary tuberculosis (TB) in three districts of South India, 2015-2018(N=765)

Characteristic	Frequency (%)
Sputum Smear Grading at Diagnosis	
1+	241 (31.5)
2+	255 (33.3)
3+	269 (35.2)
Karnofsky Score at diagnosis	
50-60	218 (28.5)
>60	547 (71.5)
HIV Status	
Sero-positive	5 (0.6)
Sero-negative	760 (99.4)
Random Blood sugar	
<200mg/dl	531 (69.4)
≥200mg/dl	234 (30.6)
Any other Co-morbidity*	
Yes	154 (20.2)
No	611 (79.8)
Body Mass Index	
< 18.5	470 (61.4)
18.5 – 22.9	221 (28.9)
23 – 24.9	42 (5.5)
25 and above	29 (3.8)
Not recorded	3 (0.4)

Alcohol Use †	
Ever	446 (58.3)
Never	319 (41.7)
Tobacco Use ‡	
Former	140 (18.3)
Current	231 (30.2)
Never	394 (51.5)

*Other co-morbidities such as asthma, hepatitis, renal disease, cancer and breathing difficulty were reported by the participants

† Alcohol use- Alcohol use was measured for the past one year

‡Tobacco use- current or prior habitual use of both smoke and smokeless form of tobacco

Table 3: Components of household food insecurity among households of pulmonary tuberculosis (TB) patients in three districts of South India, 2015-2018. (N=765)

Occurrence Questions	Occurrence*			
	No	Rarely	Sometimes	Often
I. Worry or anxiety about food				
1.worry that the household would not have enough food	648 (84.7)	52 (6.8)	62 (8.1)	3 (0.4)
II. Insufficient Quality of Food				
2. Any household member not able to eat the kinds of foods preferred because of lack of resources	636 (83.1)	67 (8.8)	60 (7.8)	2 (0.3)
3. Eat a limited variety of foods due to a lack of resources	680 (88.9)	40 (5.2)	45 (5.9)	0 (0.0)
4. Any household member have to eat some foods that really did not want to eat because of a lack of resources to obtain other types of food	611 (79.9)	53 (6.9)	91 (11.9)	10 (1.3)
III. Insufficient Quantity of Food				
5. Any household member have to eat a smaller meal than needed because there was not enough food	593 (77.5)	73 (9.5)	97 (12.7)	2 (0.3)
6. Eat fewer meals in a day because there was not enough food	601 (78.6)	89 (11.6)	73 (9.5)	2 (0.3)

7.There ever no food to eat of any kind in your household because of lack of resources to get food	625 (81.7)	73 (9.5)	60 (7.8)	7 (0.9)
8. Any household member go to sleep at night hungry because there was not enough food	643 (84.1)	70 (9.2)	51 (6.7)	1 (0.1)
9. Any household member go a whole day and night without eating anything because there was not enough food	631 (82.5)	73 (9.5)	57 (7.5)	4 (0.5)

*0=No, 1 = Rarely (once or twice in the past four weeks), 2 = Sometimes (three to ten times in the past four weeks), 3 = Often (more than ten times in the past four weeks)

Table 4: Association of socio-demographic, morbidity, and behavioural characteristics with household food insecurity among individuals with pulmonary TB in Puducherry, N= 765

Characteristics	Total	Food insecurity*	Unadjusted PR† (95% CI) ‡	Adjusted PR†, § (95%CI) ‡
Total	765	261(34.1)	-	-
Age (in years)				
15-29	130	48 (36.9)	1.4 (0.9-2.0)	1.2 (0.7-2.2)
30-44	229	86 (37.6)	1.4 (1.0-1.9)	1.4 (0.9-2.2)
45-59	292	96 (39.9)	1.2 (0.9-1.7)	1.2 (0.8-1.8)
60 and above	114	31 (27.2)	1.0	Ref
Gender				
Male	611	203 (33.2)	1.0	Ref
Female	154	58 (37.7)	1.1 (0.91.4)	1.2 (0.8-1.8)
Marital Status				
Never Married	132	42 (31.8)	0.9 (0.7-1.2)	-
Married/Living together	567	196 (34.6)	1.0	-
Separated/divorced/ widowed	66	23 (34.9)	1.008 (0.7-1.4)	-
Education (years of schooling)				
No formal Education	131	40 (30.5)	1.0	-
1-5	160	54 (33.7)	1.10 (0.8-1.5)	-
6-10	317	114 (34.0)	1.2 (0.9-1.6)	-
>10	157	53 (33.8)	1.1 (0.8-1.6)	-
Employment				
Employed	588	206 (35.0)	1.1 (0.9-1.4)	1.4 (1.0-2.0)

Unemployed	177	55 (31.7)	1.0	Ref
Household Income per month (in INR)				
< 3000	80	41 (51.3)	1.9 (1.3-2.4)	2.0 (1.3- 3.0)
3000-5000	296	107 (36.2)	1.3 (1.0-1.6)	1.3 (0.9-1.7)
5001-10000	279	80 (28.7)	1.0	Ref
>10000	94	24 (25.5)	0.9 (0.6-1.3)	0.9 (0.6-1.6)
Didn't answer	16	9 (56.3)	2.0 (1.2-3.1)	2.2 (1.1-4.5)
Number of individuals in house				
≤3	604	198 (32.8)	1.0	Ref
>3	161	63 (39.1)	1.2 (0.9- 1.5)	1.3 (0.9-1.8)
Residence‖				
Urban	338	114 (33.7)	1.0	-
Rural	409	143 (34.0)	1.03 (0.8-1.3)	-
Number of earners in the household				
None	15	5 (33.3)	1.0	-
One	509	177 (34.8)	1.04 (0.5-2.2)	-
Two or more	241	79 (32.8)	0.9 (0.5-2.1)	-
Sputum Smear Grading at Diagnosis				
1+	241	68 (28.2)	1.0	Ref
2+	255	93 (36.5)	1.3 (1.0-1.7)	1.3 (0.9-1.7)
3+	269	100 (37.2)	1.3 (1.0-1.7)	0.4 (0.1-1.3)
Karnofsky Score at diagnosis				
50-60	218	97 (44.5)	1.5 (1.2-1.8)	1.5 (1.1-1.9)
>60	547	164 (30.0)	1.0	Ref
HIV Status				
Sero-positive	5	3 (60.0)	1.0	-
Sero-negative	760	258 (34.0)	0.6 (0.3-1.2)	-
Random Blood sugar				
<200mg/dl	531	197 (37.1)	1.4 (1.1-1.7)	1.1 (0.8-1.6)

≥200mg/dl	234	64 (27.4)	1.0	Ref
Any other Co-morbidity				
Yes	154	53 (34.4)	1.01 (0.8-1.3)	-
No	611	208 (34.0)	1.0	-
Body Mass Index‖				
< 18.5	470	177 (37.7)	1.2 (1.0-1.5)	1.06 (0.8-1.4)
18.5 – 22.9	221	68 (30.8)	1.0	Ref
23 – 24.9	42	12 (28.6)	0.9 (0.6-1.6))	0.9 (0.5-1.9)
25 and above	29	3 (10.3)	0.3 (0.1-1.0)	0.4 (0.1-1.3)
Alcohol Use				
Ever	446	160 (35.9)	1.1 (0.9-1.4)	-
Never	319	101 (31.7)	1.0	-
Tobacco Use				
Former	140	51 (36.4)	1.2 (0.9-1.5)	-
Current	231	86 (37.2)	1.2 (0.9-1.5)	-
Never	394	124 (31.5)	1.0	-

*Level of Food insecurity was assessed using the Household Food Insecurity Assessment Scale (HFIAS) for Measurement of Food Access-FANTAIII

†PR- Prevalence ratio

‡ CI-Confidence Interval

§ Adjusted for characteristics with p-value<0.2 in the univariate model

‖ Residence - Data is missing for 18 participants, Body Mass Index- Data is missing for 3 participants

ANNEXURE 1

Household Food Insecurity Access Scale (HFIAS) Measurement Tool

Occurrence Questions	Occurrence[1]			
	No	Rarely	Sometimes	Often
I. Worry or anxiety about food				
1.worry that the household would not have enough food				
II. Insufficient Quality of Food				
2. Any household member not able to eat the kinds of foods preferred because of lack of resources				
3. Eat a limited variety of foods due to a lack of resources				
4. Any household member have to eat some foods that really did not want to eat because of a lack of resources to obtain other types of food				
III. Insufficient Quantity of Food				
5. Any household member have to eat a smaller meal than needed because there was not enough food				
6. Eat fewer meals in a day because there was not enough food				
7.There ever no food to eat of any kind in your household because of lack of resources to get food				
8. Any household member go to sleep at night hungry because there was not enough food				

9. Any household member go a whole day and night without eating anything because there was not enough food				

10=No, 1 = Rarely (once or twice in the past four weeks), 2 = Sometimes (three to ten times in the past four weeks), 3 = Often (more than ten times in the past four weeks)

HFIA category

- 1 = Food Secure
  - HFIA category = 1 if [(Q1a=0 or Q1a=1) and Q2-Q9=0]
- 2=Mildly Food Insecure Access
  - HFIA category = 2 if [(Q1a=2 or Q1a=3 or Q2a=1 or Q2a=2 or Q2a=3 or Q3a=1 or Q4a=1) and Q5-Q9=0]
- 3=Moderately Food Insecure Access
  - HFIA category = 3 if [(Q3a=2 or Q3a=3 or Q4a=2 or Q4a=3 or Q5a=1 or Q5a=2 or Q6a=1 or Q6a=2) and Q7-Q9=0]
- 4=Severely Food Insecure Access
  - HFIA category = 4 if [Q5a=3 or Q6a=3 or Q7a=1 or Q7a=2 or Q7a=3 or Q8a=1 or Q8a=2 or Q8a=3 or Q9a=1 or Q9a=2 or Q9a=3]

STROBE Statement for Quantitative Part (cohort) of Study

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1,3
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	3,4
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	6-7
Objectives	3	State specific objectives, including any prespecified hypotheses	7
Methods			
Study design	4	Present key elements of study design early in the paper	8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	8-9
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	9
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	Not Applicable
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	9-10
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	9-10
Bias	9	Describe any efforts to address potential sources of bias	9-11
Study size	10	Explain how the study size was arrived at	10
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10
		(*b*) Describe any methods used to examine subgroups and interactions	10
		(*c*) Explain how missing data were addressed	10
		(*d*) If applicable, explain how loss to follow-up was addressed	Not applicable
		(*e*) Describe any sensitivity analyses	Not applicable
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	12
		(b) Give reasons for non-participation at each stage	12
		(c) Consider use of a flow diagram	Not applicable
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	12
		(b) Indicate number of participants with missing data for each variable of interest	12
		(c) Summarise follow-up time (eg, average and total amount)	Not applicable
Outcome data	15*	Report numbers of outcome events or summary measures over time	12
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	12
		(*b*) Report category boundaries when continuous variables were categorized	12
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	12
Discussion			
Key results	18	Summarise key results with reference to study objectives	13-14
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	4-5, 15
Generalisability	21	Discuss the generalisability (external validity) of the study results	5
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	17