Is a Differentiated Care Model needed for Patients with TB? A cohort analysis of outcomes among TB patients in two states in south India.

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Abstract

Background India's National Strategy to 'End TB by 2025' aims to reduce unfavourable TB treatment outcomes. There is need for innovative approaches to improve TB treatment outcomes.

Methods Under a USAID-THALI, Community Health Workers using a pre-designed tool assessed TB patients in three states in south India for risks of non-adherence and risk of unfavourable outcomes. We examined whether those with identified risk had higher levels of two unfavourable treatment outcomes; death and unfavourable outcome including death, lost to follow up and failure, as compared to no risk. Bivariate and multivariate logistic regression was used to assess each of the individual risks and the combined risk, for experiencing death or unfavourable outcome as described earlier, after initiation of TB.

Results A significantly higher likelihood of death and experiencing unfavourable outcomes was observed for individuals having one risk (AOR: 3.28; 95% CI: 2.11-5.10 for death; AOR 1.71; 95% CI: 1.29-2.26 for unfavourable outcome) and more than one risk (AOR: 4.19; 95% CI: 2.47-7.11 for death; AOR 2.21; 95% CI: 1.56-3.12) as compared to TB patients with no identified risk. In addition to the risk characterisation, TB patients with initial weight below the national median weight were 2.1 times and 2.0 times more likely to die and experience unfavourable outcomes, as compared to patients with initial weight equal to the median or higher.

Conclusion The results of our analysis point to the need for a 'differentiated care model', beginning with a risk and needs assessment and continuing with tailored care and support for TB patients, based on their identified risk. While all TB patients require a minimum package of care and support there are a substantial proportion who require more specific interventions and services in order to successfully complete their treatment. We identified a number of important risk factors that could be predictive of an unfavourable outcome and which could be used by TB programs in order to optimize patient treatment outcomes.

Introduction

India contributes 27% of the global burden of Tuberculosis and 24% of Drug Resistant TB (DR-TB) patients. Globally, almost every third death as a result of TB is from India[1]. The Government of India plans to 'End TB' through its National Strategic Plan (NSP) - India 2017–2025 and has set ambitious targets for successful treatment outcomes by 2025; 92% for DS-TB and 75% for DR-TB[2]. As per the TB India Report 2018, successful treatment outcomes were lower at 85% for DS-TB and 47% for DR-TB[3].

In India, diagnostic and treatment services are provided by the Revised National Tuberculosis Control Program (RNTCP) [3]. The program aims to enhance favourable treatment outcomes, including cure or complete treatment and consequently to reduce unfavourable treatment outcomes, including death, lost to follow up and treatment failure. TB treatment outcomes tend to be unfavourable among those with co-existing conditions such as diabetes and HIV, those who have regular alcohol consumption or smoking habits, those aged below 25 years and above 50 years, and those who have received previous treatment

for TB [4–6]. According to the India TB report 2019, based on the TB notifications in the 2017, the unfavourable treatment outcome including death was 9.3% in India, 8.6% in Telangana and 14.9% in Karnataka. The experience of death was 4.0% in India and Telangana and 6.2% in Karnataka [7].

In general, patient's adherence to treatment ensures better health outcomes, particularly for disease that require longer duration of treatment. The lack of adequate food, poor communication between healthcare providers and patients, beliefs in traditional healing systems, non-availability of TB services in nearby health facilities, side-effects and pill burden of the drugs, and stigma and discrimination were cited as reasons for poor adherence in qualitative studies that assessed barriers to treatment adherence [8, 9]. It is recommended that treatment outcomes could be improved when a package of treatment adherence interventions are offered to patients on TB treatment, such as health education and counselling, digital medication monitoring, material supports to the patient, psychological support to patient and family and staff education [10].

Despite this knowledge, most TB patients are treated similarly by the RNTCP, with little or no differentiation in the intensity or scope of care and support to patients, with some exceptions for TB-HIV and DR-TB patients. All TB patients receive routine care by TB health visitors (TBHV), who are supervised by Senior TB treatment Supervisors (STS). The RNTCP field staff are minimally trained to assess and identify risks to non-adherence, or to provide individualised counselling to help the patient cope with and overcome treatment adherence challenges.

The United States Agency for International Aid (USAID) funded the Tuberculosis Health Action Learning Initiative (THALI), implemented by Karnataka Health Promotion Trust (KHPT), in partnership with TB Alert India and St John's Medical College and Hospital, in three states in south India. THALI is a patient centred, family focused project that aims to enhance TB notification and treatment outcomes among vulnerable urban populations. The project designed and implemented a 'Differentiated Care Model (DCM)' to explore whether identifying risks to non-adherence during treatment initiation and acting to mitigate those risks, would result in better treatment outcomes. The DCM therefore begins with characterising patients based on their risk to poor adherence to treatment at the time of treatment initiation, and intensively supports those with higher risk with tailored care, in order to help them adhere to treatment and to have better treatment outcomes. This paper aims to validate whether the risks listed were significantly associated with unfavourable treatment outcomes and the odds of an unfavourable outcome in the presence of the risk.

Methods

Study Setting

After an initial start-up in two large cities namely, Bengaluru in Karnataka and Hyderabad in Telangana, the project in the third year, refined its approach and scaled up to other select towns and cities in Karnataka, Telangana and Andhra Pradesh states. This paper pertains to analyses of patients only from Karnataka and Telangana, the states with a consistent presence, since the start of the project. The

selected geographies covered a total population of 18.6 million urban people in 15 districts of Karnataka and 8.1 million urban people in 6 districts of Telangana. In total, this covered 69 cities/towns and that included 61 in Karnataka and 8 in Telangana. In these selected cities/town the project recruited Community Health Workers (CHWs) who are local residents, to conduct systematic and consistent outreach activities. The outreach activities included, awareness generation on TB, referrals of symptomatic cases, risk and need assessment of patients initiated on TB treatment, treatment follow-ups, contact screening and counselling as required.

Study tools

In consultation with RNTCP staff, the project developed two tools for the TB patients who were initiated on treatment. One tool is known as the Risk and Needs Assessment (RANA) tool and is used to identify the persons with probable risks and those who expressed specific needs during the TB treatment. The second tool is known as Prevention Care and Support Card (PCS) and is used to register the patient for follow-up visits and record the information on activities, test results and actions taken, during each follow-up visit until the treatment outcome is declared.

The project technical team trained the CHWs for a week to administer the tools, using classroom and field sessions. This was followed up by on-the-job supportive supervision by a cadre of cluster coordinators (CC), who were recruited in the ratio of 1 CC: 5 CHWs. The RANA tool was pre-tested for two weeks in Bengaluru and Hyderabad, and adapted for simplicity and uniformity in assessment, recording and interpretation of the data before its administration in the project.

Study procedure

First, we obtained the line list of all the persons diagnosed with TB in the project geographies from the respective RTNCP staff. After that we administered the RANA tools as well as registered the patients who consented for follow-up visits using the PCS. We included only the TB patients who were residing within the towns/cities in the project geographies. The RANA was administered to the patient and in rare instances when the patient was not able to provide the information himself/herself, due to being hearing impairment or being very sick, it was collected from the primary care-giver in the family.

The RANA tool assessed the patient's understanding of TB and its treatment, explored family level support for the patient, listed social, nutritional and livelihood needs, identified factors that were presumed to be a risk for non-adherence to TB treatment and noted the type of follow-up preferred (in-person or other) by the patient. Each interview took about 25-40 minutes, and was conducted in a venue convenient to the patient, such as the home or the place of treatment. Initially, paper-based entries were computerised onto a Management Information System. Subsequently, the project combined data collection and entry using a mobile app. RANA was administered in Bengaluru and Hyderabad from June, 2018 and in other cities and towns it was administered from August, 2018.

RNTCP Operational definitions

The following provides the RTNCP operational definition of treatment outcomes [11].

Cured: A microbiologically confirmed TB at the beginning of the treatment who was smear or culture-negative at the end of complete treatment.

Treatment success: TB patients either cured or treatment completed are accounted in the treatment success.

Died: Known to have died from any cause whatsoever while on treatment

Failure: A TB patient whose biological specimen is positive by smear or culture at the end of the treatment.

Lost to follow-up: A TB patient whose treatment was interrupted for one consecutive month or more.

Not evaluated: A TB patient for whom no treatment outcome is assigned. (Formerly transfer out).

Treatment regimen changed: Previously, it was called as switched over to MDR treatment.

Died, Failure and Lost to follow up were considered together as unfavourable TB treatment outcomes.

Data analysis

We combined three different data sets in order to perform our analysis. For the risk identification we used the data from the RANA. For obtaining the outcome we used the THALI PCS data as well as the official RNTCP data from the Nikshay. The data-sets were linked using a unique identity number and validating it for age and gender. At the beginning of August 2019, we extracted data of patients who were 18 years or older at the time of TB diagnosis and notification, and whose RANA had been carried out in the months of July, August and September 2018. The patients had been initiated on TB treatment, 0-8 months prior to the administration of RANA, with a mean of about 2 months. We restricted the analysis to this cohort of patients mainly in order to ensure that we had treatment outcomes for majority of the patients. We also wanted to avoid the effect of an envisaged differentiated care model that we were piloting for TB patients identified to have a risk for non-adherence to treatment. The treatment outcomes were extracted from the PCS card as on July 31, 2019 or earlier, about 10-12 months after treatment initiation. In case, the treatment outcome was not available in the PCS data, we extracted treatment outcome from the Nikshay data. In the analysis, we included only the patients who had data on outcome declared by the month of July 2019, and who also had both RANA and PCS card. The data analysis included only the patients from Karnataka and Telangana states.

We defined two outcome indicators for the analysis. The first outcome measured was ‘death’, after initiation of TB treatment. The other indicator was ‘unfavourable outcome’ which included death, failure or Lost to Follow Up (LFU). The analysis includes separate results for predefined risk conditions which the individuals have, as well as the risk identified as having one risk or more than one risk.

The data was analysed using Stata version 14. We examined the socio-economic and demographic characteristics of the TB patient cohort as defined. Based on empirical knowledge and available evidence, we considered the following factors as potential risks for non-adherence to treatment: 1) age above 60 years, 2) living alone, 3) co-existing illness including HIV, 4) diabetes and 5) undernutrition, 6) previous treatment for TB, 7) a diagnosis of drug-resistant TB and 8) a history of regular (daily) consumption of alcohol. Information on risk factors listed above were recorded based on patient's history and/or documented laboratory reports (HIV, diabetes), as applicable.

Undernutrition was not one of the risk factors identified initially. While we aimed to use BMI as our indicator of malnutrition, anthropometric measurements were not feasible for a large number of patients. Hence, we used weight at the time of treatment initiation as our measure and categorised it based on whether it was below or equal to and greater than the median weight of TB patients as recorded in the National Guideline on Nutrition and TB, viz., 43 kg for males and 38 kg for females [12].

We first conducted bivariate analysis to understand whether the presence of any of the above considered risk factors were associated with the two outcome indicators, viz., death and unfavourable TB treatment outcome. Subsequently, we applied multivariate logistic regression to determine the independent effect of each of the individual risk factors, as well as combined risk factor on the two outcomes. We considered two multivariate logistic regression models. In the first multivariate logistic regression model, we considered the risk characterisation based on all the seven stated risks as well as the other background characteristics of the patient. In the second model, we considered the individual risk factors along with the other background characteristics of the patient.

Ethical approval

Ethics approval for program data review and analysis was obtained from the Institutional Ethics Committee of St John's Medical College and Hospital. Regulatory approval for access to Nikshay data and to interview of patients and subsequent follow-up visits, was provided by the State TB office and local RNTCP officials in the two states.

Results

Characteristics of the respondent

Overall data was available for 4749 TB patients, resident in THALI project geographies within the states of Karnataka, and Telangana. THALI PCS data provided treatment outcome data for 4075 patients and for the remaining 674 patients, data was obtained from Nikshay. The patient's background and risk characteristics, on the basis of the RANA tool, are given in Table 1. Nearly, two-thirds of the patients were from Karnataka and the remaining 34% were from Telangana. Females constituted 38% of patient population. Overall, 70% of the patients were of Hindu religion, 45% were either non-literate or completed less than fifth grade, about 21% having completed 10th grade. 73% were currently married. A little above three-fourths were diagnosed with pulmonary TB and the remaining 24% with extra-pulmonary TB. The

analysis revealed that for about 19% of the patients, the initial weight was either not measured or not documented. The weight of 22% of the patients, who had an initial weight measurement, was below the median value reported for the all India level according to sex of the person (43kg for males and 37kg for females), and the remaining 59% had a weight that was equal to or above the median value.

The distribution of risk classes shows that 12% of TB patients assessed were aged 60 or above, 13% consume alcohol, 4% live alone, 16% were previously treated for TB, 2% were reported to be HIV positive and 5% reported to have diabetes. Overall, 30% were identified to have only one of these seven stated risks, and 11% have more than one risk.

Treatment Outcomes

The results of the analysis of two treatment outcomes examined, viz., 'death' and 'unfavourable outcome', are provided in Table 2. In total, about 3% experienced death and 6% experienced unfavourable outcomes. Patients whose treatment outcome was death and or considered to be unfavourable were comparatively higher in Karnataka (3% and 8%). Higher proportion of males (3% and 8%), patients belonging to religions, other than Hindus and Muslims (5% and 8%), either illiterate or those who had studied until the fifth standard (4% and 8%), and whose marriage was dissolved (4% and 8%), experienced higher death rates and unfavourable outcomes, as compared to their counterparts. Patients with initial weight that was less than the national median value experienced higher death rates and unfavourable outcomes (4% and 10%), as compared to patients with initial weight equal to the national level median or higher (2% and 5%).

Patients who classified as having more than one of the stated risks had experienced higher deaths (6% versus 1%) as well as unfavourable outcomes (12% versus 4%) than those without any of the stated risks. Similarly, patients having only one of the stated risks also had experienced higher deaths (5%) and unfavourable outcomes (8%).

Risk Factors Identification

Table 3 indicates the results using logistic regression to determine the odds ratios and adjusted odds ratios of the patient experiencing death or unfavourable outcome as a whole, according to background characteristics and any risk. Patient with more than one of the stated risk factors have significantly higher likelihood of dying and experiencing unfavourable outcomes as compared to patients who don't have any of the seven risks (AOR: 4.19; 95%CI: 2.47-7.11 for death; AOR: 2.21; 95% CI: 1.56-3.12). We also identified initial weight and education status below matriculation (10th grade) of the patient as significantly affecting the risk of death and of experiencing unfavourable outcome. TB patients with initial weight below the median weight were 2.1 times (95%CI: 1.38-3.14) and 2.0 times (95%CI: 1.50-2.61) more likely to die and experience unfavourable outcomes, as compared to patients with initial weight equal to the median or higher. Patients from Karnataka have significantly higher unfavourable outcomes as compared to patients from Telangana (AOR: 2.35; 95%CI: 1.71-3.23). Also, the experience of unfavourable outcome was significantly more among males as compared to females (AOR: 1.63; 95% CI: 1.20-2.21).

The results of the logistic regression that considered the seven risk factors individually are given in Table 4. Out of the seven risk factors considered, four factors, including patients who are aged 60 and above (AOR: 2.15; 95%CI: 1.37-3.37), who consume alcohol (AOR: 2.09; 95%CI: 1.35-3.25), who are previously treated for TB (AOR: 1.65; 95%CI: 1.08-2.51), and who are HIV positive (AOR: 4.75; 95%CI: 2.29-9.86), were significantly more likely to experience death, as compared to patients who do not have such risks. As per the results of the unfavourable outcomes, age of the patient was not a significant risk factor, though we found this as a significant risk factor for death. Additionally, patient who are DR-TB patients were significantly more likely to experience the unfavourable outcome including death, failure and LFU as compared to patient without DR-TB (AOR: 2.33; 95%CI: 1.41-3.87). The effect of initial weight below the median was found to be significantly higher for both death (AOR: 1.98; 95%CI: 1.30-3.00) and unfavourable outcome (AOR: 1.89; 95%CI: 1.43-2.50).

When we considered all the seven risk factors individually into the model, patients in Karnataka experienced significantly higher deaths (AOR: 1.55; 95%CI: 1.01-2.35) as well as unfavourable outcome (AOR: 2.46; 95%CI: 1.79-3.39) as compared to Telangana. Among the socio-economic factors considered, educational status of the patient above 10th standard was found to have significant reverse risk association with death independently as an outcome and in combination as unfavourable outcome in comparison with those with less education. The odds of males experiencing the unfavourable outcome was 1.7 times (95%CI: 1.24-2.30) higher than females.

Discussion

Early diagnosis and initiation of treatment of TB plays major role in the prevention and control of TB. Once treatment is initiated, it is important that all the patients complete the treatment successfully. The Directly Observed Treatment Short-course (DOTS) or DOT for daily treatment has been adopted in many countries to support treatment adherence. However, it is possible that not all patients require direct observation to complete their treatment. Besides, following and observing every patient has both human resource limitations and cost implications. In this situation, it is therefore important to identify which patients are at high risk of experiencing unfavourable outcomes such as death, failure and lost to follow-up and to ensure that at least all of these high-risk patients are provided with a more intensified follow up. This is an essential first step in a “differentiated care model”.

The differentiated care model is well known among people living with HIV (PLHIV). This model has been successfully used to categorise stable versus unstable PLHIV in order to provide differential care [13]. In India, PLHIV with TB are screened regularly using a four symptom screening, are a priority group for diagnosis by Cartridge based Nucleic Acid Amplification Test (CB-NAAT), are recommended for early initiation of anti-tuberculosis treatment (ATT) using fixed dose combinations for daily TB treatment and for early initiation of anti-retroviral treatment (ART). The ‘differentiated care’ is provided by ART centres, which are staffed by a multidisciplinary team of doctors, counsellors, nurse, pharmacist and others. Similarly, the Government of India has established a wide network of labs across the country to enable early diagnosis of DR-TB and has created DR-TB nodal treatment centres in almost every district, staffed

by doctors, laboratory technicians and counsellors. Thus, TB patients with HIV or DR-TB have greater access to more rapid, individualised and more comprehensive care, from multi-skilled teams. Our analysis identifies at least 4-5 other categories of patients that require intensive and personalised care from a team of care providers.

We found that only five of these seven risk characteristics significantly influence the experience of death and/or unfavourable outcomes. Diabetes and living alone did not turn out to be significantly associated with the experience of death or with unfavourable outcome. However, an additional factor, viz., initial weight of less than the national median weight value for males and females with TB, was identified as an independent risk factor for death and unfavourable outcome. We intended to use body mass index as the measure for malnutrition. However, measurements of weight and height were not feasible for many patients in the field situation. Moreover, the measurements were taken at different times during the course of the disease and its treatment. Hence, we chose the single indicator of whether the initial weight that was measured was lower, or equal to and greater than the median, as referred to in the handbook on Nutrition and TB. While this may be a very crude measure, it is fairly simple and straightforward, for even an illiterate patient or front-line field worker to recognise and comprehend. Male gender was identified as an independent risk factor for unfavourable outcome, but not for death, indicating that behaviour related to alcohol or smoking could probably be confounding this variable. The proportion of males who consume alcohol or smoked were much higher than females.

Previous studies have indicated diabetes as a contributor to the incidence of TB and to unfavourable outcomes among those on treatment. We did not find a similar association in our study. The probable reason for this finding is that diabetes screening among TB patients was not universal and was captured only from patient reports that were available. The prevalence of diabetes in the general population ranges from 12-18%, while it is less than 5% among the TB patients in our analysis. This indicates that the diagnosis of diabetes could have been missed, because of the lack of universal screening of TB patients for diabetes. This could have resulted in misclassification of the patients with and without diabetes, because of non-availability of blood sugar results. The incidence of symptoms of peripheral neuropathy in patients with TB and diabetes tends to be high [14]. This side effect, can be easily prevented and managed when identified during an intensive follow-up. Hence, identification of diabetes among TB patients and a close monitoring of diabetic status would still be important in a differentiated care model, even though it did not stand out significantly in our analysis. Additionally, we would strongly recommend the universal screening of all TB patients above 30 years of age for diabetes, in order to not miss the diagnosis of a co-morbidity.

Similarly, age above 60 years was not independently associated with an unfavourable TB treatment outcome in the multifactorial logistic regression analysis, though it was significantly associated with higher rates of death. The risk of death is high and therefore these patients require additional supports. Maybe, TB death in this age is confounded by other co-morbidities. We therefore feel that we still need to include age above 60 years within the differentiated care model, because these TB patients may require

more intensive care and support, in order to prevent untimely death, whether directly as a result of TB or because of other underlying disease conditions, which should be adequately screened for and addressed.

The risk of unfavourable outcomes appears to be higher in Karnataka, when compared to the neighbouring states. Whether this is due to more accurate reporting of death or whether it is a result of other human development indicators, needs further examination.

Some of the limitations of our study include the following. Previous studies have indicated age below 25 years as a risk factor for poor outcomes. Our analysis was restricted to those above the age of 18 and the number between 18-25 was not large enough to analyse this variable. More recently, program data points out that girls in adolescence tend to have more TB than boys [7]. The treatment outcomes in adolescence and childhood will need to be further studied. In rare instances, we noted inconsistency between Nikshay reported outcomes and our data. We used our recorded outcome as we were able to validate this directly from the patient or a family member. For 14% of patients, we depended on Nikshay, as we did not have outcome recorded in our database. The characteristics of this group of patients were not independently analysed to examine whether any differences existed between this group and those for whom we had treatment outcomes recorded in the PCS. Finally, since the RANA administration was carried out on an average of almost 2 months after the initiation of treatment, there could be underestimation of deaths as about 50% of TB deaths occur within two months of treatment initiation [15].

Conclusions

Enhancing favourable treatment outcomes for DS TB to 92% and DR-TB to 75% requires innovative approaches. The Differentiated Care Model (DCM), with an initial Risk and Needs Assessment (RANA), appears to be an essential first step innovation, in order to identify those at greater risk of an unfavourable treatment outcome, or death. The provision of follow up comprehensive care that addresses specific needs of all TB patients is often not feasible. However, it will be important to ensure that all patients who have been identified to have one or more risks associated with experiencing any unfavourable outcome or death alone are followed up intensively and are provided with a differentiated care approach, that addresses their specific treatment-related, social, nutritional, behavioural and psychological needs.

TB patients have diverse disease, demographic and behavioural characteristics. These characteristics are easily obtained from history and are expected to be recorded for TB patients on the Nikshay platform. Therefore, identifying patients with these risk factors is feasible in India, if a risk and needs assessment is carried out and documented into Nikshay in a systematic manner. Data analytics can be directly built into the system to highlight a patient who needs differentiated care approach. The study has indicated few of the risks that are important for assessment of whether a TB patient requires more specific comprehensive care or whether routine care is sufficient. The fields for all these risk factors are configured on the current Nikshay platform, but are rarely given due attention.

The study also provides a model, with process and tools to implement this innovation at scale. The impact of the differentiated care model on improving outcomes among TB patients will be evaluated in a subsequent paper.

Abbreviations

AOR: adjusted odds ratio; ART: anti-retroviral treatment; ATT: anti-tuberculosis treatment; CB-NAAT: cartridge based nucleic acid amplification test; CC: cluster coordinators; CHW: community health workers; CI: confidence interval; DCM: differentiated care model; DOTS: directly observed treatment short-course; DR-TB: drug resistant TB; DS-TB: drug sensitive TB; HIV: human immunodeficiency virus; LFU: Lost to Follow-up; NSP: national strategic plan; PCS: prevention care and support card; PLHIV: people living with HIV; RANA: risk and needs assessment; RNTCP: Revised National Tuberculosis Control Program; STS: senior TB treatment supervisors; TB: tuberculosis; TBHV: TB health visitor; THALI: tuberculosis health action learning initiative; USAID: United States Agency for International Aid.

Declarations

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Availability of data and materials

Some restrictions will apply with sharing the data. Data cannot be shared publicly without the approval form the donor agency and the concerned RNTCP office.

Authors contributions

RW,,PKH, KK, PBS, SJ and MB designed the DCM approach. RW, RSP, KK, PBS, PKH, BS, RD, and VP supported in the development and finalization of the study tools. RSP, SJ, PBS, BKM, RD and BS trained the field staff. RD, VP, BKM and BS coordinated and supervised the data collection and data entry. VP and HLM supported administratively for the data collection. RSP did the statistical analysis and interpreted the results. RW and RSP written the first draft of the manuscript. MB, PBS, SJ, BS, RD, AK, AR, ST, AS, RS, AS, VP and HLM offered comments on the draft and critically revised the manuscript. All authors read and approved the final manuscript.

Ethics approval and consent to participate

Regulatory approvals for the study were from the respective State Tuberculosis Office and respective local RNTCP officials. Ethical approval was obtained from the Institutional Ethics Committee of St John's Medical College and Research Institute, Bengaluru, India. Oral informed consent was taken from all the participants.

Consent for publication

Not applicable

Competing interests

The authors have declared that no competing interests exist.

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Tables

Table 1: Percent distribution of TB patients according to selected background characteristics and risk conditions

Characteristics	Percent	Number of cases
Name of the State		
Karnataka	66.4	3153
Telangana	33.6	1596
Sex		
Female	37.8	1797
Male	62.2	2952
Initial weight[1]		
Below median value	22.8	1081
Median value or above	60	2850
Unknown	17.2	818
Religion		
Hindu	70.0	3326
Muslim	26.3	1249
Others	3.7	174
Education status		
< 5 Standard	44.8	2126
5-10 Standard	33.9	1612
Above 10 Standard	21.3	1011
Marital Status		
Single	22.0	1046
Married	72.5	3443
Marriage dissolved	5.1	240
Not known	0.4	20
Type of TB		
Extra Pulmonary TB	24.4	1158
Pulmonary TB	75.6	3591
Age		
Below 60	88.0	4178
60 and above	12.0	571
Previously treated for TB		
No	84.0	3989
Yes	16.0	760
DR TB		
No	97.1	4611
Yes	2.9	138
Drink alcohol		
No	87.1	4135
Yes	12.9	614
Living alone		
No	96.1	4565
Yes	3.9	184
HIV		
Negative	98.2	4662
Positive	1.8	87
Diabetes		
No	95.1	4518
Yes	4.9	231
Number of risk present[2]		

No risk	58.9	2797
Only one risk present	30.0	1424
More than one risk present	11.1	528
Total percent	100	4749

Note: Included patients aged 18 years and above whose RANA was administered between July and September and also treatment outcome was declared

[1]Considered median value of 43 Kgs for males and of 38 Kgs for females

[2]Risk present include, aged 60 and above, previously treated patients, DR TB patients, using alcohol, living alone, HIV positive patient, Diabetes patient

Table 2: Percent of patients experienced either death or experienced unfavourable outcomes[3] according to selected characteristics and risk conditions

Characteristics	Experienced death	Experienced unfavourable outcome	Number of cases
Name of the State			
Karnataka	3.1	7.7	3153
Telangana	2.0	3.2	1596
Sex			
Female	2.1	3.6	1797
Male	3.1	7.8	2952
Initial weight[1]			
Below median value	4.3	10.0	1081
Median value or above	1.8	4.5	2850
Unknown	3.7	7.1	818
Religion			
Hindu	2.7	6.5	3326
Muslim	2.5	5.2	1249
Others	4.6	7.5	174
Education status			
< 5 Standard	4.0	7.7	2126
5-10 Standard	2.5	6.6	1612
Above 10 Standard	0.5	2.3	1011
Marital Status			
Single	1.5	5.0	1046
Married	3.0	6.4	3443
Marriage dissolved	3.8	7.9	240
Not known	0.0	10.0	20
Type of TB			
Extra Pulmonary TB	1.8	3.5	1158
Pulmonary TB	3	7.0	3591
Age			
Below 60	2.3	5.9	4178
60 and above	5.4	7.9	571
Previously treated for TB			
No	2.3	5.3	3989
Yes	4.9	10.8	760
DR TB			
No	2.6	5.9	4611
Yes	6.5	16.7	138
Drink alcohol			
No	2.2	5.4	4135
Yes	5.9	11.1	614
Living alone			
No	2.7	6.2	4565
Yes	2.2	6.0	184
HIV			
Negative	2.6	6.0	4662
Positive	11.5	16.1	87
Diabetes			
No	2.7	6.2	4518
Yes	2.2	4.8	231
Number of risk present[2]			

No risk	1.2	4.0	2797
Only one risk present	4.5	8.4	1424
More than one risk present	6.1	11.9	528
Total percent	2.7	6.2	4749

Note: Included patients aged 18 years and above whose RANA was administered between July and September and also treatment outcome was declared

[1]Considered median value of 43 Kgs for males and of 38 Kgs for females

[2]Risk present include, aged 60 and above, previously treated patients, DR TB patients, using alcohol, living alone, HIV positive patient, Diabetes patient

[3]Unfavourable outcome includes death, failure and LFU patients.

Table 3: Results of multivariate logistic regression for experienced death and experienced unfavourable outcomes according to background characteristics and number of risk present

Characteristics	Experienced death					Experienced unfavourable outcome[3]				
	UOR	AOR	95% CI		p-value	UOR	AOR	95% CI		p-value
Name of the State										
Telangana (Reference)	1.00	1.00				1.00	1.00			
Karnataka	1.55	1.42	0.94	2.16	0.099	2.52	2.35	1.71	3.23	<0.001
Sex										
Female (Reference)	1.00	1.00				1.00	1.00			
Male	1.53	0.97	0.64	1.48	0.883	2.28	1.63	1.20	2.21	0.002
Initial weight[1]										
Median value or above (Reference)	1.00	1.00				1.00	1.00			
Below median value	2.45	2.08	1.38	3.14	<0.001	2.38	1.98	1.50	2.61	<0.001
Weight unknown	2.05	2.12	1.32	3.38	0.002	1.64	1.74	1.25	2.43	0.001
Religion										
Muslims (Reference)	1.00	1.00				1.00	1.00			
Hindus	1.09	0.97	0.64	1.48	0.888	1.26	1.09	0.81	1.46	0.573
Others	1.89	1.84	0.81	4.15	0.143	1.47	1.44	0.76	2.72	0.261
Education status										
Above 10 Standard (Reference)	1.00	1.00				1.00	1.00			
< 5 Standard	8.28	5.39	2.11	13.79	<0.001	3.59	2.68	1.67	4.31	<0.001
5-10 Standard	5.12	3.96	1.53	10.22	0.004	3.02	2.41	1.50	3.86	<0.001
Marital Status										
Single (Reference)	1.00	1.00				1.00	1.00			
Married	2.01	1.06	0.60	1.87	0.839	1.30	0.88	0.63	1.24	0.472
Marriage dissolved	2.51	0.93	0.38	2.26	0.872	1.64	1.07	0.59	1.94	0.815
Not known	NE	NE	NE	NE	NE	2.12	2.67	0.57	12.44	0.211
Type of TB										
Extra Pulmonary TB (Reference)	1.00	1.00				1.00	1.00			
Pulmonary TB	1.68	1.00	0.99	0.60	1.632	0.98	1.31	0.92	1.86	0.138
Number of risk present[2]										
No risk (Reference)	1.00	1.00				1.00	1.00			
Only one risk present	3.94	3.28	2.11	5.10	<0.001	2.21	1.71	1.29	2.26	<0.001
More than one risk present	5.40	4.19	2.47	7.11	<0.001	3.28	2.21	1.56	3.12	<0.001

Note: Included patients aged 18 years and above whose RANA was administered between July and September and also treatment outcome was declared. UOR – Unadjusted odds ratio. AOR – Adjusted odds ratio. CI – Confidence Interval.

[1]Considered median value of 43 Kgs for males and of 38 Kgs for females

[2]Risk include, aged 60 and above, previously treated patients, DR TB patients, using alcohol, living alone, HIV positive patient, Diabetes patient

[3]Unfavourable outcome includes death, failure and LFU patients.

Table 4. Result of multivariate logistic regression for experienced death and experienced unfavourable outcomes considering background characteristics and individual risks

Characteristics	Experienced death					Experienced unfavourable outcome[2]				
	UOR	AOR	95% CI		p- value	UOR	AOR	95% CI		p- value
Name of the State										
Telangana (Reference)	1.00	1.00				1.00	1.00			
Karnataka	1.55	1.54	1.01	2.35	0.045	2.52	2.46	1.79	3.39	<0.001
Sex										
Female (Reference)	1.00	1.00				1.00	1.00			
Male	1.53	0.95	0.61	1.48	0.825	2.28	1.69	1.24	2.30	0.001
Initial weight[1]										
Median value or above (Reference)	1.00	1.00				1.00	1.00			
Below median value	2.45	1.98	1.30	3.00	0.001	2.38	1.89	1.43	2.50	<0.001
Weight unknown	2.05	1.96	1.22	3.15	0.005	1.64	1.70	1.22	2.37	0.002
Religion										
Muslims (Reference)	1.00	1.00				1.00	1.00			
Hindus	1.09	0.94	0.62	1.45	0.788	1.26	1.10	0.82	1.47	0.544
Others	1.89	1.71	0.75	3.91	0.205	1.47	1.40	0.74	2.66	0.304
Education status										
Above 10 Standard (Reference)	1.00	1.00				1.00	1.00			
< 5 Standard	8.28	5.38	2.10	13.83	<0.001	3.59	2.74	1.71	4.41	<0.001
5-10 Standard	5.12	3.99	1.55	10.31	0.004	3.02	2.41	1.51	3.87	<0.001
Marital Status										
Single (Reference)	1.00	1.00				1.00	1.00			
Married	2.01	1.09	0.62	1.93	0.763	1.30	0.95	0.68	1.34	0.779
Marriage dissolved	2.51	0.88	0.35	2.23	0.795	1.64	1.22	0.66	2.24	0.523
Not known	NE	NE	NE	NE	NE	2.12	3.23	0.70	14.96	0.133
Type of TB										
Extra Pulmonary TB (Reference)	1.00	1.00				1.00	1.00			
Pulmonary TB	1.68	1.09	0.66	1.80	0.737	2.06	1.37	0.96	1.95	0.081
Age										
Below 60 (Reference)	1.00	1.00				1.00	1.00			
60 and above	2.39	2.15	1.37	3.37	0.001	1.36	1.12	0.79	1.60	0.533
Previously treated for TB										
No (Reference)	1.00	1.00				1.00	1.00			
Yes	2.17	1.65	1.08	2.51	0.020	1.58	1.18	2.11	0.00	0.003
DR TB										
No (Reference)	1.00	1.00				1.00	1.00			
Yes	2.61	1.83	0.86	3.89	0.117	3.22	2.33	1.41	3.87	0.001
Drink alcohol										
No (Reference)	1.00	1.00				1.00	1.00			
Yes	2.71	2.09	1.35	3.25	0.001	2.16	1.38	1.01	1.88	0.043
Living alone										
No (Reference)	1.00	1.00				1.00	1.00			
Yes	0.79	0.68	0.24	1.89	0.460	0.75	0.40	1.42	0.38	0.473
HIV										
Negative (Reference)	1.00	1.00				1.00	1.00			
Positive	4.96	4.75	2.29	9.86	<0.001	3.01	2.61	1.41	4.82	0.002
Diabetes										

No (Reference)	1.00	1.00				1.00	1.00			
Yes	4.96	0.74	0.29	1.86	0.521	0.75	0.70	0.37	1.32	0.266

Note: Included patients aged 18 years and above whose RANA was administered between July and September and also treatment outcome was declared. UOR – Unadjusted odds ratio. AOR – Adjusted odds ratio. CI – Confidence Interval. NE – Not estimated.

[1]Considered median value of 43 Kgs for males and of 38 Kgs for females

[2]Unfavourable outcome includes death, failure and LFU patients.