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ORIGINAL ARTICLE

Programmatic implications of a sub-national TB prevalence survey in India

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SUMMARY

BACKGROUND: Subnational TB estimates are crucial for making informed decisions to tailor TB control activities to local TB epidemiology.

METHODS: A cross-sectional survey was conducted among 143,005 individuals in Tamil Nadu, India. Participants were screened for symptoms and underwent chest X-ray (CXR). Participants with symptoms of TB and/or abnormal CXR were tested for TB using Xpert, smear, and liquid culture.

RESULTS: The prevalence of microbiologically confirmed pulmonary TB (MCPTB) was 212 (95% CI 184–239) per 100,000 population. The prevalence-to-notification ratio (P:N) in the state was 2.05 (95% CI 1.8–2.29). Low body mass index and diabetes together had a population attributable fraction of 54.15 (95% CI 45.68–61.97). Approximately 39% of the TB cases were asymptomatic and were identified only by CXR screening. In the general population, only 26.9% sought care at a health facility among those with symptoms suggestive of TB.

CONCLUSION: The programme needs to prioritise screening with CXR to potentially detect cases earlier and curtail the transmission and upscale molecular tests in the selected population to increase the yield of case finding. Innovative health education strategies must be devised to address health-seeking behaviour.

KEY WORDS: tuberculosis; prevalence; India; TB epidemiology; TB programme

India contributes to 26% of global TB incidence and 36% of TB mortality.[1] The Government of India has set an ambitious goal for eliminating TB by reducing the incidence of new TB cases by 80% by 2025 compared with 2015.[2] In India, a national TB prevalence survey was conducted during 2019–2021 and has estimated the prevalence at the national and state levels to monitor the progress of TB control activities in the country.[3] The burden of TB is usually distributed heterogeneously within countries. Policy decisions, planning, and budgeting for TB control activities are largely decentralised and occur at subnational levels. To tailor control activities to local TB epidemiology, subnational TB estimates are crucial to make informed decisions.[4] Tamil Nadu, a southern state in India, has a higher burden of TB cases compared to the national average.[3] There is a high level of commitment from the state health system towards TB elimination, and with its renowned public health infrastructure, the State has devised its own strategy for "TB free Tamil Nadu".[5] Local TB control programmes will have to devise innovative strategies to control TB burden based on the local prevalence and health-seeking behaviour specific to the local population.[6] We describe the results of the state-wide TB prevalence survey conducted in the general population during 2021–2022 in Tamil Nadu, with the objectives of estimating the prevalence of microbiologically confirmed pulmonary TB (MCPTB) disease among individuals 15 years and above, all forms of TB in all age groups (extrapolated from the measured burden). When prevalence measurements are compared with official case notification data, prevalence surveys can identify gaps in detection and reporting.[7] We also report the prevalence-to-notification ratio (P:N) in Tamil Nadu. We also describe health-seeking behaviour, risk factors for TB, and programmatic implications of the survey.

METHODS

Study design, size, and setting

India is divided into administrative subdivisions that include many states. Tamil Nadu is one such state that is further subdivided into districts. Each district is divided into wards in urban areas and villages in rural areas. A cross-sectional survey was conducted to estimate the prevalence of MCPTB in all 33 districts of Tamil Nadu from February 2021 to July 2022. A target sample size of 144,000 was calculated, assuming 0.00119 as the average expected prevalence of pulmonary TB in Tamil Nadu, with varying relative precision (d) for the districts, 0.4 as cluster variation, 85% coverage, and design effect of 1.5. Considering the feasibility of implementation, we planned 180 clusters with 800 as the cluster size. We

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adopted a multistage cluster sampling design. The number of clusters in each district was allocated according to the population (population proportionate to size).

Participants and screening procedures

The enumeration of participants included the details of all family members in the household to determine eligibility for participation. The study population included participants aged $\geq$15 years and residing in the selected village/urban census enumeration block for the previous month. Hospitalised residents, institutional populations, and seriously sick/bedridden patients were excluded. All eligible participants underwent screening by interviews and digital CXR (chest X-ray). Trained medical officers classified CXR into normal and abnormal on the spot in the field. Participants having symptoms suggestive of TB (cough >2 weeks, fever >2 weeks, blood in sputum, chest pain >1 month, weight loss, loss of appetite, expectoration and night sweats), history of TB treatment (previous/current), and abnormal CXR (any lung, including pleura, abnormality detected on interpretation by the medical officer (e.g., opacities, cavitation, fibrosis, pleural effusion, calcification(s), any unexplained or suspicious shadow) were eligible for sputum examination. Pregnant women were exempted from X-ray screening and were eligible for sputum examination only if they had symptoms. In addition, CXRs were also read by a panel consisting of two pulmonologists at the district level, and if there were any discrepancies, a third umpire reading was performed within 48–72 h to capture abnormalities and thereby decide on sputum eligibility. X-ray abnormalities reported by either the field medical officer or the panel were eligible for sputum examination.

Laboratory procedures

One spot sputum sample was collected and subjected to cartridge-based nucleic acid amplification test (CBNAAT) for the detection of *Mycobacterium tuberculosis* and rifampicin resistance in nearby CBNAAT sites. A second sputum sample was collected and transported to a pre-identified quality-assured reference laboratory for smear microscopy (SM) and liquid culture (LC). A conditional third sputum sample was collected (in case the first sample tested positive for CBBNAAT) and underwent SM, LC, and CBNAAT in the reference laboratory to minimise false-positives. As soon as the sputum results were available, the details of the participants diagnosed with TB were shared with the local TB programme staff to initiate treatment at the earliest. Care was taken to ensure that the team leaves the particular cluster only after ensuring proper referrals of all diagnosed TB cases.

Survey case definition

A participant with two bacteriological (based on CBNAAT, SM or LC) or one bacteriological with one radiological evidence of TB was defined as MCPTB.

Data management and analysis

Field data were collected electronically, including data from reference laboratories and the teleradiology panel. This information was entered into an online web application for the TB prevalence survey. All the analysis was conducted in STATA/MP v15.1 (Stata, College Station, TX, USA). To estimate the crude and adjusted prevalence of MCPTB, logistic regression with robust standard errors was used to account for the cluster design of the survey.[8] The adjusted estimation considered missing information on disease status among those eligible for sputum collection. Multiple missing value imputation was performed using the "*mi*" and chained equation (i.e., "*ice*"), and inverse probability weighting accounted for non-participation.[9]

The prevalence of all forms of TB for all ages and the prevalence-to-notification (P:N) ratio for 2021 were calculated. Univariate generalised linear models were used to assess the strength of the association between risk factors and TB by calculating the relative risk (RR) with 95% confidence intervals (CIs). Furthermore, the population attributable fraction (PAF) with 95% confidence intervals (CIs) was calculated using Levin's formula.[10]

Ethical considerations

Written informed consent was obtained from eligible participants above 18 years of age and the parent/guardian of 15–18-year-old participants. Written assent was also obtained for 15–18-year participants. The study protocol was approved (017/NIRT-IEC/2021) by the Institutional Human Ethics Committee, National Institute for Research in Tuberculosis, Chennai, India.

RESULTS

Approximately 223,709 household members were enumerated, of whom 143,005 (63.9%) were found eligible and invited for the survey. Of those eligible, 130,932 (91.6%) participants consented to participate in the survey. Among the eligible participants, the participation of males was 40.7% (n = 53,298) and that of females was 59.3% (n = 77,622). The participation rate was higher in rural clusters (93.4%) than in urban clusters (89.6%). Among the participants, 130,914 (99.9%) underwent symptom screening and 125,870 (96.1%) underwent both symptom screening and CXR examination.

Table 1. Characteristics of study participants with crude prevalence.

	Overall *n* (%*)	TB *n* (%†)	Crude prevalence‡ /100,000 (95% CI)
Age, years			
15–24	20,271 (15.5)	10 (0)	50 (19–80)
25–34	21,105 (16.1)	12 (0.1)	57 (25–90)
35–44	26,003 (19.9)	21 (0.1)	81 (47–116)
45–54	25,590 (19.5)	54 (0.2)	212 (155–268)
55–64	21,408 (16.4)	73 (0.3)	341 (263–420)
≥65	16,555 (12.6)	74 (0.4)	447 (346–549)
Sex			
Female	77,622 (59.3)	59 (0.1)	77 (57–96)
Male	53,298 (40.7)	185 (0.3)	348 (298–398)
Transgender	12 (0)	0 (0)	
Area			
Rural	68,763 (52.5)	147 (0.2)	214 (180–249)
Urban	62,169 (47.5)	97 (0.2)	157 (126–188)
BMI			
Extremely underweight [<16.5]	5,975 (4.6)	46 (0.8)	770 (549–992)
Underweight [16.5–18.4]	10,923 (8.3)	69 (0.6)	632 (484–781)
Normal [18.5–24.9]	63,379 (48.4)	96 (0.2)	152 (122–182)
Pre-obesity [25.0–29.9]	35,335 (27)	27 (0.1)	77 (48–106)
Obesity - I [30.0–34.9]	11,821 (9)	5 (0)	43 (6–80)
Obesity - II [35.0–39.9]	2,685 (2.1)	0 (0)	
Obesity - III [≥40.0]	796 (0.6)	1 (0.1)	126 (0–372)
Self-reported smoking status			
Non-smoker	117,091 (89.4)	151 (0.1)	129 (109–150)
Past smoker	5,410 (4.1)	31 (0.6)	574 (372–775)
Current smoker	8,413 (6.4)	62 (0.7)	737 (555–920)
Self-reported alcohol status			
Non-alcoholic	1,11,641 (85.3)	129 (0.1)	116 (96 - 136)
Past alcoholic	6,299 (4.8)	46 (0.7)	731 (521 - 941)
Current alcoholic	12,974 (9.9)	69 (0.5)	532 (407 - 657)
Diabetes mellitus			
No	1,11,763 (85.4)	182 (0.2)	163 (140 - 187)
Not known	6,490 (5)	7 (0.1)	108 (28 - 188)
Yes	12,661 (9.7)	55 (0.4)	435 (320 - 549)

* Column percentage.
† Row percentage.
‡ Crude prevalence with binomial exact confidence level.
CI = confidence interval; BMI = body mass index.

TB cases and their prevalence

Based on the case definition, 244 microbiologically confirmed PTB patients were identified in the survey (Table 1). Of the 244 TB cases, 224 (91.8%) were currently not receiving treatment. Of the 244 cases diagnosed in the survey, 191 (85.3%) were diagnosed for the first time with TB, 20 (8.2%) were currently on TB treatment, and 33 (14.7%) with a past history of TB were currently not on treatment. Among the 244 patients with TB, only 54.5% ($n = 133$) reported having symptoms, whereas 92.6% ($n = 224$) had CXR abnormalities. The crude prevalence of MCPTB among individuals aged ≥15 years was 186/100,000 (95% CI 163–210. The participant characteristics with a crude prevalence of TB for age group, sex, place of survey, body mass index (BMI), self-reported smoking and alcohol status, and self-reported diabetic status (Table 1). The adjusted prevalence of MCPTB among individuals aged ≥15 years in Tamil Nadu was 212/100,000 (95% CI 184–239). The prevalence of all forms of TB among all age groups in Tamil Nadu was 210/100,000 (95% CI 183–237). The state P:N ratio (smear/CBNAAT prevalence to notification for adult PTB) was 2.05 (95% CI 1.8–2.29). The P:N ratio in males was 6.23 (95% CI 5.4–7.03) compared with 0.57 (95% CI 0.43–0.71) in females.

Risk factors

The analysis showed that 47.1% ($n = 115$) of the TB cases were attributed to low BMI (BMI <18.5 kg/m^2), 47.1% to alcohol consumption, 38.1% ($n = 93$) to smoking, 22.5% ($n = 55$) to diabetes mellitus (DM), and 14.3% ($n = 35$) to past episodes of TB (Table 2).

Usefulness of CBNAAT and CXR

A total of 113/244 (53.6%) TB cases were CBNAAT-positive but smear-negative. There were 115 cases out of the 244 TB cases who had symptoms suggestive of TB and CXR abnormality. In this group, the TB positivity rate by CBNAAT was 89% (102/115) compared with 50% by smear (58/115). There were 94 TB cases (39%) who had no symptoms suggestive of TB, were not on anti-TB treatment, did not have any past history of TB. They were subjected to sputum examination purely based on the CXR abnormality criteria and were found to be bacteriologically positive.

Table 2. Population attributable factors for selected modifiable exposures associated with TB in Tamil Nadu, India.

	Screened n (%)		TB n (%)		Crude RR (95% CI)	PAF (95% CI)
BMI, kg/m^2						
≥18.5	1,14,034	87.1	129	52.9	Reference	Reference
<18.5	16,898	12.9	115	47.1	6.02 (4.72–7.67)	39.32 (32.44–6.26)
DM						
Non-DM	1,18,271	90.33	189	77.46	Reference	Reference
DM	12,661	9.67	55	22.54	2.72 (2.01–3.67)	14.26 (8.90–20.52)
Self-reported smoking status						
Non-smoker	1,17,109	89.44	151	61.89	Reference	Reference
Smoker	13,823	10.56	93	38.11	5.22 (3.93–6.94)	30.82 (23.63–38.54)
Self-reported alcohol status						
Non-alcoholic	1,11,659	85.28	129	52.87	Reference	Reference
Alcoholic	19,273	14.72	115	47.13	5.16 (3.94–6.77)	37.98 (30.20–45.93)
Past history of TB						
No past TB	1,29,182	98.66	209	85.66	Reference	Reference
With past TB	1,750	1.34	35	14.34	12.36 (8.63–17.71)	13.18 (9.25–18.26)
Two or more comorbidities						
BMI ≥18.5 + DM	1,01,822	77.8	87	35.7	Reference	Reference
BMI ≥18.5 + DM	29,110	22.2	157	64.3	6.31 (4.78–8.33)	54.15 (45.68–61.97)
BMI ≥18.5 + non-DM + non-smoker	91,370	69.8	49	20.1	Reference	Reference
BMI <18.5 or DM or smoker	39,562	30.2	195	79.9	9.19 (6.62–12.76)	71.22 (62.93–78.04)
BMI ≥18.5 + non-DM + non-smoker + non-alcoholic	84,310	64.4	32	13.1	Reference	Reference
BMI <18.5 or DM or smoker or alcoholic	84,310	64.4	32	13.1	10.38 (7.36–14.64)	76.66 (69.02–82.69)
BMI ≥18.5 + non-DM + non-smoker + non-alcoholic + past TB	84,310	64.4	32	13.1	Reference	Reference
BMI <18.5 or DM or smoker or alcoholic or past TB	46,622	35.6	212	86.9	11.98 (8.26–17.39)	79.63 (72.09–85.37)

RR = relative risk; CI = confidence interval; PAF = population attributable function; BMI = body mass index; DM = diabetes mellitus.

Health-seeking behaviour

Among the 9,540 symptomatic patients, only 2,574 (26.9%) had sought health care, and among those who sought care, 62.7% sought care in public health facilities and the remaining approached private care. The main reasons for not seeking care were ignoring symptoms (85.8%), self-treatment (3.1%), and affordability issues (1.2%). Among 2,574 who approached a healthcare facility, only 793 (30.8%) underwent a sputum examination and only 863 (33.3%) underwent CXR. Among the symptomatic patients, 2,432 (25.5%) had alcohol consumption in the present or past and 2,096 (22%) had smoking in the past or present. Similarly, only 133/244 (54.5%) of the MCPTB patients had TB symptoms, and among them, only 44 (33.1%) sought care for their symptoms. Of the 44 TB cases who sought care for their symptoms, sputum examination was performed in only 50.0% (n = 22) and CXR was performed in only 54.6% of them (n = 24).

DISCUSSION

The TB prevalence survey among individuals aged ≥15 years in Tamil Nadu was the state's first prevalence survey ever conducted. The prevalence of MCPTB among adult males was 348 (95% CI 298–398), which was almost four times higher than that among females (77, 95% CI 57–96). Furthermore, the gap in P:N is six times higher in males than in females, suggesting that men are more likely to develop TB but less likely to be diagnosed. This could be due to a higher burden, lower care-seeking, or a combination. Similar findings were observed in surveys conducted in Pakistan and the Philippines.[11,12] The observation of higher TB prevalence among males compared with females was similar to the notification data and other prevalence surveys conducted in Asia.[11,13] The higher burden of TB may be due to physiology, as sex hormones modulate the immune responses necessary for resistance to TB in females.[14] Understanding the role of sex hormones and sex-related genetic regulations, among other factors, in susceptibility differences will help in developing future interventions.[14] We also noted a higher prevalence in individuals aged ≥65 years (447, 95% CI 346–549) than in the other age groups. It was noted that the prevalence increased as the age group increased, which indicates that there is a shift in the epidemiology of TB towards older age group. This also suggests that there are more cases of TB reactivation and older people may have poor access to TB care. Similar findings were observed in the recently conducted prevalence survey in Myanmar and the national survey in India.[3,15,16] The prevalence was higher among participants with BMI <18.5 kg/m^2, DM, alcohol consumption, and smoking, which was similar to the results from the national survey.[3] All these are known risk factors for PTB, and it would be reasonable to say that the trend also applies in the state of Tamil Nadu. Similar findings have been reported in various other studies.[17–20]

The P:N ratio was 2.05 (95% CI 1.8–2.29) and it was similar to that in the national survey.[3] This is, however, lower than that of Indonesia (5.1) and higher than that of Myanmar (1.7).[4,15] The health-seeking behaviour of the symptomatic was low as the majority ignored the symptoms and did not recognise it as illness. Even among those who sought care, the majority did not undergo either sputum or CXR examination. This might be an important factor because only 8.2% of the TB cases were currently undergoing treatment, and the remaining cases would have been missed or diagnosed late if the survey was not conducted. Among the symptomatic patients who sought care, the majority (62.7%) approached the public health system, which is contrary to the national data where the public (49%) and private (49.7%) contributions were equal.[3] This may suggest a better opportunity for Tamil Nadu State to strengthen TB control efforts in the public health system. Among the 244 identified TB cases, 33 participants had a past history of TB (14.7%), which was lower than the proportion reported in the national survey (24%).[3] This is one of the indicators for the programme which is better than the national average. These differences from the national survey also highlight the importance of subnational estimates in a large, diverse country like India, which in turn helps to plan and prioritise strategies according to local needs.

Of the 20,086 individuals eligible for sputum examination, 10,546 (52.5%) were eligible based only on CXR abnormality. Among the 244 TB cases detected, 94 (36%) had no symptoms, which would have been missed if CXR was not used. Although these cases might have been eventually detected with TB at a later time period, these delays will increase the potential pool of transmission.[21,22.] This is very crucial for high-burden settings where the rate of decline in TB incidence is far from the elimination target. Similar findings have been reported in prevalence surveys in other Asian TB prevalence surveys and a prevalence survey in South Africa.[17,23] The TB programme in Tamil Nadu currently offers CXR only for those with symptoms, whereas the survey offered CXR to all eligible participants except pregnant women. This is an important programmatic implication that also needs to be considered because the yield of CXR screening can also be influenced by factors such as the quality of X-ray equipment, expertise of the interpreters, and availability of other diagnostic tools like sputum testing or molecular tests. Among the 244 MCPTB, *M. tuberculosis* was detected by CBNAAT in 224 (91.8%), whereas acid-fast bacilli (AFB) smear was positive in 123 (50.40%). This shows that molecular diagnostic method like CBNAAT has a higher detection rate in TB diagnosis. The programme currently relies on smear on a large scale and must scale up molecular tests. The yield using CBNAAT must be closely examined in surveys because there may be false-positives due to already treated cases having dead bacilli. However, in this survey, even among the symptomatic TB cases ($n = 115$), 89% ($n = 102$) were diagnosed by CBNAAT compared with 58 (50%) who were diagnosed based on smear results. This clearly shows that molecular tests should be upscaled, at least in symptomatic individuals, to diagnose TB considering the costs involved in screening everyone with molecular testing in developing countries.

Our study had certain limitations. Due to logistic issues, there were some time delays in culture reporting, which could have led to contamination and underreporting of culture-positives in the survey. Culture testing was the top challenge faced in various other prevalence surveys. Proper planning and capacity building of laboratories are necessary to avoid culture delays due to the high load of samples received during TB surveys.[24]

CONCLUSION

More interventions, such as nutritional interventions for the malnourished, old age screening, and interventions for promoting smoking and alcohol cessation, need to be scaled up for better control of PTB. Emphasis on health education by various means and strategies is required to improve symptom awareness among the general community and to improve healthcare-seeking behaviour and thereby break the chain of transmission. Upscaling of molecular testing and CXR screening should be considered to enhance TB case findings, without which marching towards TB elimination will be impossible.

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Data availability and sharing: A subset of the key anonymised individual participant data collected during the study, along with a data dictionary, is available upon request to the corresponding author after approval of a proposal with a signed data access agreement.

Conflicts of interest: none declared.

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RÉSUMÉ

CONTEXTE : Les estimations infranationales sur la TB sont essentielles pour orienter les actions de lutte contre la maladie en fonction de l'épidémiologie locale.

MÉTHODES : Une étude transversale a été réalisée sur 143 005 individus dans le Tamil Nadu, en Inde. Les participants ont subi un dépistage des symptômes et une radiographie pulmonaire (CXR). Ceux présentant des symptômes de TB et/ou une radiographie anormale ont été testés pour la TB à l'aide du test Xpert, d'un prélèvement et d'une culture en milieu liquide.

RÉSULTATS : Le taux de prévalence de la TB pulmonaire microbiologiquement confirmée (MCPTB) s'élevait à 212 (IC à 95% 184–239) pour 100 000 habitants. Le rapport de prévalence/notification (P:N) dans l'État était de 2,05 (IC à 95% 1,8–2,29). L'indice de masse corporelle bas et le diabète étaient responsables ensemble d'une fraction attribuable à la population de 54,15 (IC à 95% 45,68–61,97). Environ 39% des cas de TB étaient asymptomatiques et n'ont été détectés que grâce au dépistage CXR. Dans la population générale, seuls 26,9% ont cherché à recevoir des soins dans un établissement de santé parmi ceux présentant des symptômes évocateurs de TB.

CONCLUSION : Le programme devrait accorder la priorité au dépistage par CXR pour détecter les cas plus précocement et enrayer la transmission, ainsi qu'à l'amélioration des tests moléculaires dans la population ciblée pour augmenter l'efficacité de la recherche de cas. Il est nécessaire de développer des stratégies innovantes d'éducation à la santé pour améliorer les comportements de recherche de soins.