Screening tuberculosis patients for diabetes in a tribal area in South India

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Setting: Ten peripheral health institutions of a tribal tuberculosis unit, Saluru, Vizianagaram District, South India.

Objective: To assess among tuberculosis (TB) patients: 1) the feasibility of screening for diabetes mellitus (DM), 2) the prevalence of DM, 3) the demographic and clinical features associated with DM, and 4) the number needed to screen (NNS) to find one new case of DM.

Design: Cross-sectional study: all TB patients registered from January to September 2012 were screened for DM using a screening questionnaire and random blood glucose, followed by fasting blood glucose (FBG) measurements using a glucometer. DM was diagnosed if FBG was ≥ 126 mg/dl.

Results: Of 381 patients, 374 (98%) were assessed for DM, suggesting feasibility of screening, and 19 (5%) were found to have DM (12 were newly diagnosed and 7 had a previous diagnosis of DM). The only characteristic associated with DM was age ≥ 40 years. The NNS to detect a new case of DM among all TB patients was 31; among those aged ≥ 40 years, the NNS was 20, and among current smokers it was 21.

Conclusion: Screening of TB patients for DM was feasible and effective, and this should inform national scale-up. Other key considerations include the continued provision of free TB-DM screening, with co-location and integration of services.

India has the highest burden of tuberculosis (TB) in the world,¹ and an estimated 63 million people living with diabetes mellitus (DM).² Evidence suggests that the DM population has a significantly increased risk of developing active TB (two or three times higher than in those without DM).^{3–6} Three recently published epidemiologic studies in South India in about 1500 patients with TB found a high prevalence of DM: about 25% in Tamil Nadu,⁷ 32% in Karnataka⁸ and 44% in Kerala.⁹

A landmark project conducted by the International Union Against Tuberculosis and Lung Disease (The Union), the World Health Organization (WHO) and the national authorities in India on bidirectional screening of TB and DM, modelled on the Collaborative Framework for care and control of tuberculosis and diabetes, was implemented in eight tertiary centres and more than 60 peripheral health facilities in eight tuberculosis units (TUs), including Vizianagaram.¹⁰ The India Tuberculosis–Diabetes Study Group (ITDG) assessed the feasibility and results of screening TB patients for DM with pooled data from the project sites.¹¹ The study

showed that of 8109 TB patients who were assessed for DM, 1084 (13%) were found to have DM, based on fasting blood glucose (FBG) measurements. Based on these data, a policy decision was made by India's Revised National TB Control Programme (RNTCP) to implement countrywide screening of TB patients for DM.¹¹ One limitation of this study, however, was that it published only aggregate data from all sites, and may have missed site-specific variations, and other socio-demographic and clinical factors affecting the effectiveness and feasibility of the screening programme. We therefore analysed individual patient data and described the effectiveness of screening all TB patients for DM in one tribal TU.

The tribal area is remote and difficult to access due to poor connectivity and lack of other basic infrastructure. Indicators relating to literacy, economic status, social status and access to health care services are poor among tribes compared to the general population.¹² The tribes are in transition from a forest-centred way of life to a rural, settled farming lifestyle. Given the different lifestyle, more access to unprocessed, fibre-rich foods, including fruit and vegetables in their diet and greater daily physical activity, we hypothesized that the prevalence of DM would be considerably lower in tribal areas when compared with the rest of the country. The specific objectives of the study were to assess, among a cohort of TB patients: 1) the feasibility of screening for DM, 2) the prevalence of DM, 3) the demographic and clinical features associated with DM, and 4) the number needed to screen (NNS) to find one new case of DM among TB patients.^{13,14}

METHODS

Study design

This was a descriptive study of all TB patients attending the study TU.

Setting

The study was conducted in Saluru TU (a geographical area defined under the RNTCP as a sub-district-level programme management unit, covering a population of 250 000), with TB diagnostic and treatment services being delivered through a network of primary, secondary and tertiary health care facilities. Saluru TU is a sub-division of one of the initial 30 districts identified in India for piloting the roll-out of non-communicable disease prevention and control activities through the National Programme for Prevention of Cancer, Diabetes, Cardiovascular Disease and Stroke, with community-based screening of all individuals aged >30 years for

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DM.¹⁵ The TU is termed tribal because >70% of the population belong to one of the Scheduled Tribes.

Screening and diagnosis of DM followed national guidelines, which stipulate that FBG should be used with cut-off thresholds in line with those recommended by the WHO.¹⁶ Briefly, FBG ≥ 126 mg/dl (≥ 7 mM) indicates DM; FBG 110–125 mg/dl (6.1–6.9 mM) indicates impaired fasting glucose (IFG); and FBG < 110 mg/dl (<6.1 mM) is normal.

TB patients were categorised as 'new' and 'previously treated' based on their past history of TB treatment. The diagnosis of new smear-positive or new smear-negative TB was based on quality assured smear microscopy and chest radiography, while that of extra-pulmonary TB was based on a combination of clinical, radiological and histopathological evidence per RNTCP guidelines.¹⁷

For the screening process in TB patients, all patients attending the TU were asked by laboratory technicians or attending nurses in the health facility whether they had already been diagnosed with DM. Those who confirmed that they had DM were referred to the nearest public health facility offering DM care. Per protocol, TB patients with known DM status were not tested again. In those with no known diagnosis of DM, random blood glucose (RBG) tests were performed on capillary blood using glucometers, followed by FBG testing by the same method at the next visit if the RBG was ≥ 110 mg/dl. If patients with TB were found to have an FBG of ≥ 126 mg/dl, they were diagnosed as having presumptive DM and referred to DM services for definitive diagnosis and enrolment in care. Those with RBG of between 110 mg/dl and 126 mg/dl were considered to have IFG, and no specific action was taken, apart from informing and counselling the patients. Screening for DM and TB and all care for diagnosed cases were provided free of charge.

Study population and study period

The study was conducted from January to September 2012. All TB patients registered in the TU at the 10 peripheral health institutions (PHIs) formed the study population.

Data variables, collection and validation

The data variables relating to the study objectives were sourced from the TB register and an additional TB-DM register that was developed and used to record data from the screening questionnaire used for the purpose of the pilot study. These data were extracted to pre-tested, structured collection sheets, which were checked for completeness and consistency by TB laboratory supervisors of the programme once a week, and by the principal investigator once a fortnight. All staff involved in data collection, data validation and data entry were trained in performing the respective procedures using the study protocol and data collection sheets.

Data entry, analysis and reporting

The data were double-entered by two data entry operators into a pre-designed data entry form using EpiData software, Version 3.1 (EpiData Association, Odense, Denmark), with inbuilt checks to minimise data entry

errors. Both databases were compared and discrepancies resolved by referring to the original data collection sheets. All analyses were done using EpiData analysis software, Version 2.2.2.180. A descriptive analysis was performed to determine DM prevalence. Comparisons were then made between TB patients with and without DM using the χ^2 test. Levels of significance were set at 5%. The NNS to diagnose an additional case of DM is the reciprocal of the proportion of newly detected DM cases. We adhered to STROBE guidelines for reporting observational studies in writing this manuscript.¹⁸

Ethics approval

Local administrative approval was obtained from the District TB Centre, Vizianagaram, for conducting the study. Confidentiality was assured, as data collection sheets were maintained securely by programme staff and electronic databases contained no personal identifiers. Ethics approval was obtained from the Ethics Advisory Group of The Union.

RESULTS

The screening process for DM is shown in Table 1. Of 381 TB patients, 374 (98%) were assessed for DM and 19 (5.1%) were found to have the disease. Of these, 7 (1.9%) had a previously known diagnosis of DM and 12 (3.2%) were newly detected based on blood glucose measurements. IFG was diagnosed in 32 (8.5%) patients. Of all the TB-DM cases, four known DM cases had already been enrolled in DM care; the remaining 15 TB-DM cases were referred for DM care (3 with known DM and 12 with new DM), of whom 12 were enrolled in care.

TABLE 1 DM screening among TB patients registered under the RNTCP in Saluru TU, Vizianagaram, South India, January–September 2012

Indicator	n (%)
A Total patients registered with TB	381
B Number and proportion of (A) assessed for DM as per protocol	374 (98.2)
C Number and proportion of (B) with a known diagnosis of DM	7 (1.9)
D Patients needing to be screened for RBG	367
E Number and proportion of (D) screened with RBG	367 (100)
F Patients with RBG ≥ 110 mg/dl and needing to be screened for FBG	117
G Number and proportion of (F) screened with FBG	115 (98.3)
H Patients with FBG ≥ 126 mg/dl (newly diagnosed for DM)	12
I Patients with IFG (blood glucose levels 110–126 mg/dl)	32
J Number and proportion of (B) with known and newly diagnosed DM	19 (5.1)
K Number and proportion of (J) referred for DM care	15 (78.9)
L Number and proportion of (J) who reached DM care	12 (63.2)

DM = diabetes mellitus; TB = tuberculosis; RNTCP = Revised National Tuberculosis Control Programme; TU = tuberculosis unit; RBG = random blood glucose; FBG = fasting blood glucose; IFG = impaired fasting glucose.

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A workshop was convened in Delhi, India, for the purpose of writing the papers that are published in this supplement. The workshop was run by the Centre for Operational Research, International Union Against Tuberculosis and Lung Disease (The Union), Paris, France; The Union South-East Asia Office, New Delhi, India; the Operational Research Unit, Médecins Sans Frontières, Luxembourg; the World Health Organization Country Office in India, New Delhi, India; the All India Institute of Medical Sciences, New Delhi, India; and ESIC Medical College, Bangalore, India.

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TABLE 2 Demographic and clinical characteristics associated with DM in TB patients in Vizianagaram, South India, January–September 2012

Characteristic	TB patients without DM <i>n</i> (%)	TB patients with DM (known and newly diagnosed) <i>n</i> (%)	Total	<i>P</i> value
Total	355	19	374	
Age, years				
<40	185 (52.1)	4 (21.1)	189	<0.01
≥40	170 (47.8)	15 (78.9)	185	
Sex				
Male	221 (62.2)	15 (78.9)	236	0.14
Female	134 (37.7)	4 (21.1)	138	
Type of TB				
New	308 (86.7)	18 (94.7)	326	0.48
Previously treated	47 (13.2)	1 (5.2)	48	
HIV test				
Reactive	25 (7.04)	0	25	0.62
Non-reactive	314 (88.4)	17 (89.5)	331	
Unknown	16 (4.5)	2 (10.5)	18	
Smoking status				
Current smoker	80 (22.5)	5 (26.3)	85	0.77
Not current smoker	275 (77.4)	14 (73.6)	289	

DM = diabetes mellitus; TB = tuberculosis; HIV = human immunodeficiency virus.

Characteristics associated with DM are shown in Table 2. Age >40 years was the only factor significantly associated with a higher prevalence of DM, and no differences were observed with respect to sex, smoking status, human immunodeficiency virus (HIV) status or type of TB. Of the 19 TB-DM cases, 12 were new smear-positive TB cases, 4 new smear-negative cases, 2 new extra-pulmonary cases and one was a previously treated extra-pulmonary case (data not shown).

The NNS to detect a new case of DM is shown in Table 3. The NNS was 31 for all patients; among those aged ≥40 years, it was 20, and among smokers it was 21.

TABLE 3 Number needed to screen to detect a new case of DM among TB patients in Vizianagaram, South India, January–September 2012

Characteristic	Patients assessed for DM <i>n</i>	Patients newly diagnosed with DM (FBG ≥126 mg/dl) <i>n</i> (%)	NNS*
Total	374	12 (3.2)	31
Age, years			
<40	189	3 (1.6)	63
≥40	185	9 (4.9)	20
Sex			
Male	236	10 (4.2)	24
Female	138	2 (1.4)	69
Type of TB			
New	326	12 (3.7)	27
Previously treated	48	0	NA
Smoking status			
Current smoker	85	4 (4.7)	21
Not current smoker	289	8 (2.8)	36

*Rounded to nearest integer.

DM = diabetes mellitus; TB = tuberculosis; FBG = fasting blood glucose; NNS = number needed to screen; NA = not applicable.

DISCUSSION

A low prevalence of diabetes has been reported among tribal and rural populations in India.¹⁹ 'Lifestyle' diseases are increasing steadily, however, with the gradual domestication of tribal areas and the increased influx of tribes into the mainstream population. Sparse data are available on the prevalence of DM among TB patients, and little is known about the effectiveness of screening all TB patients among the tribal population. This is to our knowledge the first study from India to examine the screening process for DM among TB patients in a peripheral TU in a tribal area.

This study confirms that, given the setting of a tribal TU in India, screening of TB patients for DM can be effectively implemented within the existing framework of health care delivery. Questions about previous DM diagnosis and blood tests for those who have no known previous history of DM can be undertaken reliably, and the recording and monitoring system was shown to work well. The overall prevalence of DM in this tribal population, both known and newly detected, was approximately 5%. This was low compared to the overall prevalence of 9% DM among TB patients in TUs found by the ITDG,¹¹ indicating that DM prevalence is heterogeneous across geographical areas and various health settings in India. Nevertheless, the screening strategy in our study detected more new DM cases than previously diagnosed DM cases. This probably indicates a lack of awareness about DM, poor access to services for managing DM in these populations, and the potential of the screening strategy for detecting new DM cases.

Similar to findings by a study in China,²⁰ nearly 10% of new cases were diagnosed as having IFG, an indicator for a future high risk of DM or stroke.^{21,22} Co-existing TB disease could be responsible for stress-induced hyperglycaemia in some of these patients, but this is also probably an early indicator of a future risk of DM. Lifestyle modification measures and health promotion strategies may help to prevent DM in most of these patients,²² and this is something to be considered for future management, as little action was taken in our study apart from informing and counselling the patients. All of the newly detected TB-DM patients were referred to DM care services in the nearest public health facilities, and although specific data were not captured in this study, the majority of the known cases of DM were already enrolled in care.

Our study found that the prevalence of DM in TB patients was significantly associated with age ≥40 years, but did not vary by sex or type of TB. HIV positivity was associated with absence of DM, and no HIV patient was found to have DM in our study, similar to findings elsewhere.²³ A sub-analysis of the NNS to detect one new case of DM showed that it might be more cost-effective to screen patients aged ≥40 years and possibly current smokers, but this requires more formal, prospective research.

The strengths of the study are that it was implemented without any additional resources within the existing health care system and with minimum training needs. The screening of patients was well accepted in the community, with almost 100% of registered TB patients undergoing the screening process that was offered. High acceptability in the community with minimum additional resources deployed for the screening process suggests that the study is feasible.

There are some limitations to the study. First, decisions on the diagnosis of DM were based on capillary blood glucose levels, as venous blood glucose measurements were not available in the PHIs. However, the WHO states that capillary and venous blood samples should be regarded as almost identical.¹⁶ Second, the skill levels of health staff in correctly using this technology and the quality control of the glucometers were not assessed during the study. Third, the measurements of RBG and FBG may be inaccurate in

diagnosing DM. Rapid swings in blood glucose levels can occur with RBG and FBG measurements.^{24–26} It has also been accepted that FBG alone may fail to diagnose approximately 30% of cases of previously undiagnosed DM, relative to those assessed by a 75 g oral glucose tolerance test,^{27,28} which may have to be performed when indicated in certain cases to avoid delayed diagnosis of true DM. Glycosylated haemoglobin (HbA1c) provides a more stable measure of blood glucose levels over 2 to 3 months,^{24–26} but this form of measurement was too expensive and was not used in the current study. Fourth, the timing of DM screening during TB treatment can also affect blood glucose readings, and studies have shown that the prevalence of hyperglycaemia decreases over time during TB treatment.^{29–32} However, as the effect of transient hyperglycaemias on TB treatment outcomes is not fully understood, we would argue that it is better to screen patients at the earliest opportunity so that we can try to diagnose and treat DM early in the course of TB treatment. Assessing the effect of better DM control on TB treatment outcomes and on the reported risk of recurrent TB³³ was beyond the scope of this study but should be the subject of future research.

There are some key issues for policy makers to consider before implementing this strategy more widely. First, the high acceptability of DM testing among TB patients in our study was facilitated by the widespread free availability of DM testing services at all 10 PHIs. Availability of free DM testing services at all peripheral health facilities is probably a prerequisite for the successful implementation of this screening strategy. Second, the total number of DM screening tests performed will increase substantially as a result of the roll-out of this strategy, and both national programmes need to plan for enhanced procurement and supply chain management. Third, it is acknowledged worldwide that timely referral of cases for proper care and management is vital in co-morbid conditions such as HIV-TB,³⁴ and the co-location and integration of services is key to successful programme collaboration.³⁵ Similarly, the integration of DM and TB management services must be considered as scale-up takes place, and this could mark the beginning of strong cooperation and collaboration between communicable and non-communicable disease programmes.

In conclusion, our study found that the screening of TB patients for DM was feasible and effective, and in a tribal TU where prevalence rates of DM might be expected to be lower than in urban populations, we still detected one in 20 cases of DM. Age was a factor significantly associated with the prevalence of DM, and if resources are limited, it might be worth focusing the screening of TB patients on those aged ≥ 40 years.

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Contexte : Dix institutions périphériques de santé d'une unité tribale de tuberculose (TB), Saluru, district de Vizianagaram, Inde du Sud.

Objectif : Evaluer parmi les patients TB : 1) la faisabilité du dépistage de diabète (DM), 2) la prévalence du DM, 3) les caractéristiques démographiques et cliniques associées au DM, et 4) le nombre de sujets à dépister (NNS) pour trouver un nouveau cas de DM.

Schéma : Etude transversal : on a recherché le DM chez tous les patients TB enregistrés entre juillet et septembre 2013 au moyen d'un questionnaire de dépistage et d'un prélèvement au hasard du glucose sanguin suivi par des mesures du glucose à jeun au moyen d'un glucomètre. On a diagnostiqué le DM lorsque le glucose sanguin à jeun était ≥ 126 mg/dl.

Marco de referencia: Diez establecimientos periféricos de atención de salud de una unidad de tuberculosis (TB) tribal de Saluru en el distrito Vizianagaram del sur de la India.

Objective: Evaluar los siguientes aspectos en los pacientes tratados por TB: 1) la factibilidad del cribado de la diabetes sacarina (DM), 2) la prevalencia de DM, 3) las características demográficas y clínicas que se asocian con la DM, y 4) el número de personas que se debe examinar (NNS) con el fin de detectar un caso nuevo de DM.

Métodos: Se llevó a cabo un estudio transversal en el cual se practicó una detección sistemática de la DM en todos los pacientes registrados con TB entre enero y septiembre del 2012, mediante un cuestionario y una prueba de glucemia casual, seguida de una glucemia en ayunas, con el uso de un glucómetro. Se definió el diagnóstico de DM con un resultado de la glucemia en ayunas ≥ 126 mg/dl.

Resultados: De los 381 pacientes tratados por TB, se investigó la DM

Resultants : Sur 381 patients, 374 (98%) ont fait l'objet d'une évaluation pour DM, ce qui suggère la faisabilité du dépistage, et chez 19 (5%) on a trouvé un DM (12 nouveaux diagnostics et 7 diagnostics antérieurs de DM). La seule caractéristique associée avec le DM est l'âge ≥ 40 ans. Le NNS pour détecter un nouveau cas de DM pour l'ensemble des patients TB est de 31 ; parmi ceux âgés de ≥ 40 ans, le NNS est de 20 et chez les fumeurs actuels il est de 21.

Conclusion : Le dépistage du DM chez les patients TB est réalisable et efficient, et ceci devrait influencer une extension nationale. D'autres considérations-clé comportent la fourniture continue d'un dépistage gratuit TB-DM avec une co-localisation et une intégration des services.

en 374 (98%), lo cual indica la factibilidad del cribado y se estableció el diagnóstico DM en 19 pacientes (5%), de los cuales 12 fueron casos nuevos y 7 personas conocían su diagnóstico. La única característica asociada con el diagnóstico de DM fue la edad ≥ 40 años. El NNS con el fin de detectar un caso de DM en todos los pacientes con TB fue 31; en los pacientes de ≥ 40 años de edad, el NNS fue 20 y en los fumadores actuales fue 21.

Conclusión: La detección sistemática de la DM en los pacientes con TB constituye una medida factible y eficaz; estos resultados servirán para documentar las iniciativas nacionales de ampliación de escala de estas intervenciones. Otros aspectos que merecen atención especial son la provisión continua de detección de la TB y la DM sin costo alguno en un mismo centro y la integración de los servicios de atención de ambas enfermedades.