



## Is screening for diabetes among tuberculosis patients feasible at the field level?

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**Setting:** Seventeen peripheral health institutions (PHI) in Kolar district (population: 0.5 million), South India.

**Objective:** To assess the feasibility and results of screening patients with tuberculosis (TB) for diabetes mellitus (DM) at peripheral level.

**Design:** From January to September 2012, all TB patients were assessed for DM. Those with unknown DM status were screened for the disease (free of charge) by trained laboratory technicians at each PHI, using a glucometer supplied by the national programme on a capillary blood sample. Those with fasting blood glucose (FBG)  $\geq 126$  mg/dl ( $\geq 7$  mM) were diagnosed as DM-positive.

**Results:** Of 362 TB patients, 358 (99%) were assessed for DM and 62 (17.1%) had the disease—53 (14.6%) had a previous history of DM and 9 (2.9%) were newly diagnosed. All new DM patients were enrolled into DM care. Higher DM prevalence was found among TB patients aged  $\geq 40$  years, smokers and those with smear-positive pulmonary TB. To detect a new case of DM, the number needed to screen (NNS) among TB patients was 40.

**Conclusion:** Screening of TB patients for DM was feasible and effective in a peripheral setting. The availability of trained laboratory technicians and free services at every PHI made the intervention feasible. The study has contributed towards a national policy decision in this regard.

The world is facing a new epidemic of non-communicable diseases due to various factors such as urbanisation, a sedentary lifestyle, rising obesity and other lifestyle factors. In 2012, there were an estimated 371 million people living globally with diabetes mellitus (DM), with numbers expected to rise to 552 million by 2030.<sup>1</sup> India is badly affected by the DM epidemic, with over 60 million people estimated to have the disease.<sup>1</sup>

Previous studies have shown that people with DM have a higher risk of developing tuberculosis (TB) compared to those who do not have diabetes.<sup>2,3</sup> Recent studies in India have also found a high prevalence of DM in TB patients.<sup>4,5</sup> With a high DM burden in India, routine screening of TB patients for DM would appear to be worthwhile at all levels of care, including peripheral health facilities. A recently launched World Health Organization–International Union Against Tuberculosis and Lung Disease (The Union) Framework for Collaborative Activities to reduce the dual burden of DM

and TB recommends bidirectional screening of the two diseases.<sup>6</sup>

A countrywide project was conducted in 2012 to better understand the optimal screening procedures, implementation, monitoring, results and challenges of screening patients with TB for DM within eight tertiary health care settings and more than 60 peripheral health institutions (PHIs). The aggregate data of the project have been reported elsewhere.<sup>7,8</sup> In this article, we present on a more individual basis the feasibility and results of screening TB patients for DM in 17 PHIs in a district of South India, and the challenges faced during implementation.

## METHODS

### Design

This was a descriptive study involving the implementation of DM screening procedures for TB patients in routine programmatic settings.

### Setting

Bangarpet (population 0.5 million) is one of the Tuberculosis Units (TU) in the Kolar district in the southern part of India. TB diagnosis and treatment services are delivered in a decentralised manner at all the 17 PHIs of the TU. Under India's Revised National TB Control Programme (RNTCP), a PHI is defined as any health facility with a sanctioned medical officer position. All presumptive TB cases are investigated for the disease at the designated microscopy centres. After being diagnosed with TB, patients receive intermittent treatment three times a week for a period of 6–9 months, delivered under direct observation in accordance with national guidelines.<sup>9</sup> TB patients are registered and followed up until completion of treatment as per national guidelines.

While facilities for DM screening are available at all PHIs, treatment services are provided only by the specialists at the district level hospital and are continued in the PHI closest to the patient. The average distance from the PHIs to the district hospital is 35 km. Patients had to travel to the specialist hospital at their own expense. The drugs for treating DM were available in the general pharmacy and dispensed by the hospital pharmacist on prescription by the treating doctor. All services for the diagnosis and treatment of DM were provided free of charge.

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### KEY WORDS

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### Study population

All TB patients registered from January to September 2012 in 17 PHIs in Bangarpet TU were included in the study.

### Diabetes mellitus screening, variables and data collection

The methods of screening, diagnosis and referral of TB patients with DM to diabetes care have been described in detail elsewhere.<sup>8</sup> Briefly, TB patients were asked if they had a history of DM. Among those with unknown DM status, a random blood glucose (RBG) test was offered, followed by a fasting blood glucose (FBG) test if the RBG was  $\geq 110$  mg/dl ( $\geq 6.1$  mM). Blood glucose was assessed using a glucometer supplied by the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Disease and Stroke (NPCDCS) on a capillary blood sample. Those with an FBG  $\geq 126$  mg/dl ( $\geq 7$  mM) were diagnosed with DM, and those with an FBG between 110 and 125 were diagnosed with pre-diabetes (impaired fasting glucose), in accordance with national guidelines.<sup>10</sup>

Screening was performed by PHI laboratory technicians trained by NPCDCS district nodal officers as part of the strategy adopted by the NPCDCS to screen all people aged  $>30$  years at the point of primary contact with any health care facility. No additional staff were deployed for this project. Variables of interest to the study were sourced from the TB register and the TB-DM register.

### Data analysis and statistics

Data were entered in duplicate into an EpiData software package (EpiData entry version 3.1; EpiData Association, Odense, Denmark, <http://www.epidata.dk>), the databases were compared and discrepancies resolved by checking the original register. The proportion of DM cases that were 'newly diagnosed' was calculated. To find one additional DM case, the number needed to be screened (NNS) among TB patients was

**TABLE 1** Screening patients with TB for DM at 17 peripheral health institutions of the Bangarpet Tuberculosis Unit, Kolar, India, January–September 2012

Parameter	n (%)
Patients registered with TB	362
Patients with known diagnosis of DM	53 (14.6)
Number needed to be screened with RBG	309
Patients screened with RBG	305 (98.7)
Patients with RBG $\geq 110$ mg/dl ( $\geq 6.1$ mM) and needing to be screened with FBG	101
Patients screened with FBG	92
FBG results	
FBG $<110$ mg/dl ( $<6.1$ mM)	
FBG $\geq 110$ to $125$ mg/dl ( $\geq 6.1$ mM to $6.9$ mM)	72
FBG $\geq 126$ mg/dl ( $\geq 7$ mM)	11
Newly diagnosed with DM*	9 (2.9)
Patients with known or newly diagnosed DM	62 (17.1)
Patients with newly diagnosed DM enrolled in DM care	9 (100)

\*Percentage of screened patients with TB with a new diagnosis of DM. TB = tuberculosis; DM = diabetes mellitus; RBG = random blood glucose; FBG = fasting blood glucose; mM = millimoles.

determined. All variables were described as proportions, and differences between groups were compared for statistical significance using the  $\chi^2$  test or Fisher's exact test, as applicable.  $P$  values  $<0.05$  were considered statistically significant.

### Ethics approval

The protocol was reviewed and approved by The Union Ethics Advisory Group, Paris, France.

## RESULTS

There were 362 patients registered in the TU, of whom 68% were male. The median age of the cohort was 40 years (interquartile range [IQR] 27–56), and the median age of females was 30 years (IQR 21–45) compared to 45 years (IQR 32–60) among males. The results of screening are presented in Table 1. Of the 362 TB patients, 358 (99%) were assessed for DM. More than 75% of the TB patients were found to have had their RBG tested within 3 days of starting TB treatment, and among those eligible for FBG, more than 75% had had their FBG tested within 6 days of the RBG. Among the 358 patients, 62 (17.1%) were found to have DM: 53 (14.6%) had a previous history of DM and 9 (2.9%) were newly diagnosed. In addition, 11 patients were diagnosed with pre-diabetes. All newly diagnosed DM patients were referred and enrolled into DM care.

Further analysis showed that the prevalence of DM among TB patients aged  $\geq 40$  years was significantly higher than among patients aged  $<40$  years (Table 2). There was a higher prevalence of DM in new smear-positive pulmonary TB patients compared with new extra-pulmonary TB cases, and in smokers compared to non-smokers.

**TABLE 2** Prevalence of DM among TB patients according to different variables, Kolar District, India, January–September 2012

Characteristic	TB patients n	Patients with DM n (%)	P value
Total	362	62 (17.1)	
Age, years			
$<40$	173	10 (5.8)	<0.01
$\geq 40$	189	52 (27.5)	
Sex			
Male	246	43 (17.5)	0.79
Female	116	19 (16.4)	
Type of TB			
New smear-positive pulmonary TB	162	36 (22.2)	<0.01
New smear-negative pulmonary TB	45	7 (15.6)	0.20
New extra-pulmonary TB	95	8 (8.4)	Reference
Retreatment	60	11 (18.3)	0.07
Current smoker*			
Yes	157	34 (21.7)	0.04
No	205	28 (13.7)	
HIV status			
Positive	22	1 (4.5)	0.15
Negative	340	61 (17.9)	

\*Current smoker = smoked in the last month.

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

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Conflict of interest: none declared.

**TABLE 3** NNS to find an additional case of DM among TB patients, according to different variables, Kolar District, India, January–September 2012

Characteristic	a Unknown DM status <i>n</i>	b New DM among those screened <i>n</i>	a/b NNS <i>N</i>
	Characteristic	Unknown DM status <i>n</i>	New DM among those screened <i>n</i>
Total	362	9	40
Age, years			
<40	173	5	35
≥40	189	4	47
Sex			
Male	246	8	31
Female	116	1	116
Type of TB			
New smear-positive pulmonary TB	162	7	23
New smear-negative pulmonary TB	45	0	NA
New extra-pulmonary TB	95	0	NA
Retreatment	60	2	30
Current smoker*			
Yes	157	6	27
No	205	3	68
HIV status			
Negative	340	8	43
Positive	22	1	22

\*Current smoker = smoked in the last month.

NNS = number needed to screen; DM = diabetes mellitus; TB = tuberculosis; NA = not applicable; HIV = human immunodeficiency virus.

To detect a new case of DM, the NNS among TB patients was 40 (Table 3). Among the new smear-positive TB patients, the NNS was 23 compared to 30 among previously treated TB cases.

Some challenges were noted during the implementation of the screening process. There was a shortage of test kits (strips for the glucometer) for a brief period of 8 days, and the laboratory technicians used the expired strips, re-calibrating the glucometers. This was later rectified by the district programme manager of the NPCDCS, who obtained supplies of fresh batches of test strips.

## DISCUSSION

This is part of the first nationwide study from India reporting on the feasibility and outcomes of routine screening of patients with TB for DM. The results of this current study suggest that it is feasible to implement routine screening of TB patients for DM at the peripheral level. Near-universal screening of TB patients shows that testing for DM is acceptable among TB patients. The availability of staff trained in using glucometers supplied by the NPCDCS and of free DM diagnostic and treatment services helped to make this intervention feasible, with no requirement for additional resources. While most of the TB patients underwent RBG testing within 3 days of starting TB treatment, nearly 8% of those with RBG levels >110 mg/dl (6.1 mM) who were eligible for FBG did not return. The exact reasons for this are not clear, although it could be due to implementation problems in the initial stages of the pilot project.

The overall prevalence of DM among TB patients was high, at 17%, although lower than in other parts of South India.<sup>4,5</sup> The actual prevalence could be much higher, as we used FBG to diagnose DM and it is well known that FBG is not as sensitive as the 75 g oral glucose tolerance test (OGTT) and that it may miss cases of impaired glucose tolerance.<sup>11</sup> A hospital-based study conducted in Karnataka State reported a DM prevalence of 30% among TB

patients. This higher prevalence may be attributed to selection bias due to hospital-based sampling.<sup>12</sup> Previous studies from other South Indian states, such as Kerala and Tamil Nadu, reported a prevalence of 44% and 25% respectively.<sup>4,5</sup> As has been reported in earlier studies, patients aged >40 years and those with smear-positive pulmonary TB had a higher prevalence of DM.<sup>4</sup> Nearly 44% of the TB patients were smokers, and DM prevalence was higher among smokers than non-smokers. As smoking and DM are risk factors for unfavourable TB treatment outcomes and health outcomes in general, this group needs special attention and should be linked to smoking cessation services in addition to DM care. We are planning to prospectively follow the whole cohort of this study population to examine the joint impact of DM and smoking on TB treatment outcomes.

Among the DM cases found in our study, the proportion of previously diagnosed DM was high, at 86%, compared to about 50% in other studies of South India.<sup>4,5</sup> This could be attributed to the fact that Kolar is one of the 100 districts in the country where the NPCDCS has launched a programme for early diagnosis of chronic non-communicable diseases by screening all persons aged >30 years at the point of primary contact with any health care facility.<sup>6</sup> It is worth mentioning here that the RNTCP was quick to take advantage of the momentum of the screening programme launched by the NPCDCS and extend it to TB patients, with benefits for both national programmes. This universal screening strategy was one of the reasons for the relatively high NNS found in our study. Despite this fact, several new cases of DM and pre-diabetes were still found during our screening. Studies have shown that patients with pre-diabetes have a higher risk of developing type 2 DM, and they also need to be targeted for preventive interventions.<sup>13</sup>

Several challenges were noted in the supply chain management of glucometer strips, and some instances of strip shortages and expiry were experienced during field visits. The fact that laboratory staff were using the glucometer strips after expiry indicates a need for training. The NPCDCS is still in its infancy, and mechanisms need to be put in place to ensure uninterrupted supplies for smooth implementation of screening.

One of the limitations of our study is that the results obtained by the expired strips could not be excluded from the analysis, as we could not ascertain the exact number of tests performed with the expired strips or on whom they were performed in that period. Another limitation is the lack of confirmatory repeat FBG testing before making a diagnosis of DM, as recommended by the American Diabetes Association.<sup>13</sup> We did not do this in our study, as this recommendation is not included in the national guidelines in India. We are not aware whether this was done at the point of enrolment into DM care and therefore cannot comment on the implications.

This study contributed to a policy decision made by the RNTCP in India to routinely offer DM screening for all TB patients. A plan for recording, reporting and monitoring this important intervention has been prepared, and a training manual for health care providers has been drafted. There is now a need to monitor the roll-out of the intervention and lessons need to be learnt through field-based operational research. It is time to convert policy to practice and ensure implementation as per guidelines.

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**Contexte :** Dix-sept institutions de santé périphériques (PHI) du District de Kolar (population: 0,5 million d'habitants), Inde du Sud.

**Objectif :** Evaluer la faisabilité et les résultats du dépistage au niveau périphérique du diabète sucré (DM) chez les patients atteints de tuberculose (TB).

**Schéma :** Au cours de la période de janvier à décembre 2012, on a évalué tous les patients TB en matière de DM. Ceux dont le statut DM était inconnu ont été dépistés pour le DM (gratuitement) par un technicien entraîné de laboratoire dans chaque PHI sur un échantillon de sang capillaire, au moyen d'un glycomètre fourni par le programme national. Ceux dont le glucose sanguin à jeun (FBG) était  $\geq 126 \text{ mg/dl}$  ( $\geq 7 \text{ mM}$ ) ont été diagnostiqués comme DM.

**Résultats :** Sur 362 patients TB, 358 (99%) ont été évalués pour DM

et 62 (17,1%) souffraient de DM ; chez 53 (14,6%) le DM était déjà connu antérieurement et chez 9 (2,9%) le diagnostic de DM était nouveau. Tous les nouveaux patients DM ont été enrôlés pour des soins du DM. Une prévalence plus élevée de DM a été observée parmi les patients TB âgés de  $\geq 40$  ans, parmi les fumeurs et chez ceux atteints d'une TB pulmonaire à frottis positif. Pour détecter un nouveau cas de DM, le nombre de personnes à dépister (NNS) chez les patients TB est de 40.

**Conclusion :** Le dépistage du DM chez les patients TB est réalisable et efficient dans un contexte périphérique. La disponibilité de techniciens entraînés de laboratoire et le service gratuit dans chaque PHI ont rendu l'intervention réalisable. Cette étude a contribué à une décision politique nationale dans ce domaine.

**Marco de referencia:** Diecisiete establecimientos sanitarios periféricos en el Distrito de Kolar, que cuenta con una población de medio millón de habitantes en el sur de la India.

**Objetivo:** Evaluar la factibilidad de introducir una detección sistemática de la diabetes (DM) en los pacientes con tuberculosis (TB) y analizar los resultados que aportaría esta iniciativa en el nivel periférico.

**Métodos:** Entre enero y septiembre del 2012 se investigó en todos los pacientes con TB el diagnóstico de DM. En las personas que desconocían su situación frente a la DM, un técnico de laboratorio capacitado practicó el examen diagnóstico en cada establecimiento (sin costo alguno), en una muestra de sangre capilar, con el uso de un glucómetro que suministraba el programa nacional. Se estableció el diagnóstico de DM en todos los pacientes con una glucemia en ayunas  $\geq 126 \text{ mg/dl}$  ( $\geq 7 \text{ mM/dl}$ ).

**Resultados:** De los 362 pacientes con TB se investigó la DM en 358 (99%) y se estableció el diagnóstico en 62 casos (17,1%), de los cuales 53 (14,6%) conocían su diagnóstico y en nueve (2,9%) se trató de un diagnóstico nuevo. Todos los pacientes con diagnóstico reciente se inscribieron en el programa de atención de la DM. La mayor prevalencia de DM se observó en los pacientes TB a partir de los 40 años de edad, fumadores y que presentaban una TB pulmonar con baciloscopía positiva. Con el fin de detectar un nuevo caso de DM fue necesario practicar el cribado en 40 pacientes TB.

**Conclusión:** Practicar la detección sistemática de la DM en los pacientes con diagnóstico de TB constituye una estrategia factible y eficaz en un centro periférico de salud. La presencia de técnicos de laboratorio capacitados y de servicios sin costo alguno en cada establecimiento periférico hizo posible la intervención. El estudio contribuyó a una decisión de política nacional en este sentido.