



## Tuberculosis-diabetes mellitus bidirectional screening at a tertiary care centre, South India

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**Setting:** Tuberculosis (TB) and diabetes mellitus (DM) clinics at Bowring and Lady Curzon Hospital, a tertiary care centre in Bangalore, India.

**Objective:** To assess the feasibility and results of TB-DM bidirectional screening.

**Methods:** A descriptive study conducted from 1 March to 30 September 2012, in which all TB patients were assessed for DM and vice versa. Fasting blood glucose values of  $\geq 126$  mg/dl and 110–125 mg/dl were considered as DM and pre-diabetes, respectively.

**Results:** Of 510 TB patients, 32 (6.3%) had been previously diagnosed with DM. Screening among the remaining 478 patients yielded 15 (2.9%) with pre-diabetes and 15 (2.9%) newly diagnosed cases of DM. A higher prevalence of DM was found among patients aged  $\geq 40$  years, patients with pulmonary TB and smokers. Of the 47 TB-DM patients, 45 were enrolled in DM care. Of 1670 DM patients followed up in DM clinics, 45 already had TB. Among the remaining 1625 patients screened, 152 (9%) had symptoms suggestive of TB; two of these were found to have the disease.

**Conclusion:** Bidirectional screening for DM and TB is feasible and produces a high yield for DM among TB patients. The yield of TB among DM patients was low and needs future research using new, improved TB diagnostic tools.

With an annual tuberculosis (TB) incidence of 2.2 million cases (range 2.0–2.5 million) and an estimated 63 million people living with diabetes mellitus (DM), India has the highest TB burden and second highest DM burden in the world.<sup>1–3</sup> Nearly half of DM patients do not know their status, and a further 77 million people are estimated to have impaired glucose tolerance and are at higher risk of becoming diabetic.<sup>2–4</sup>

DM is known to increase the risk of active TB approximately three fold, and contributes to adverse TB treatment outcomes such as death, treatment failure and relapse.<sup>5–6</sup> The World Health Organization (WHO) and the International Union Against Tuberculosis and Lung Disease (The Union) have launched a new 'Collaborative framework for the care and control of diabetes and tuberculosis', with one of the main activities being the routine implementation of bidirectional screening of the two diseases.<sup>7</sup> Bidirectional screening aims at early detection of TB among DM patients and vice versa, and assists with an integrated approach to the management of the co-morbidity.

Available data from various sites in India show that the prevalence of DM among TB patients ranges from

25% to as high as 44%.<sup>8–10</sup> A pilot project was initiated in India in 2012 to assess the feasibility of bidirectional screening. Bowring and Lady Curzon Hospital, Bangalore, the teaching hospital of Bangalore Medical College and Research Institute in the South Indian State of Karnataka, was one of eight tertiary health facilities that participated in this pilot project. We report on the feasibility and results of bidirectional screening of TB and DM at this centre.

### METHODS

#### Design

This is a descriptive study.

#### Setting

Bowring and Lady Curzon hospital is a 570-bed multi-speciality teaching hospital in Bangalore. The outpatient department caters for an average of 900 patients per day. The hospital has a separate TB clinic and a DM clinic. TB patients diagnosed at different clinics and hospital departments are referred to the TB clinic for treatment per the Revised National TB Control Programme (RNTCP) guidelines.<sup>11</sup> An average of 1000 TB patients are treated in the TB clinic each year. The DM clinic is open 1 day a week and is visited by an average of ~100 DM patients per week.

#### Study population

All consecutively diagnosed TB patients aged  $\geq 15$  years who attended the hospital's TB clinic from 1 March to 30 September 2012 were screened for DM. At the DM clinic, all DM patients aged  $\geq 15$  years were screened for TB over the same period.

#### Screening procedures

The screening procedures and the recording and reporting tools used were as per the protocols developed for the pilot project. The details of these procedures have been described in detail elsewhere.<sup>12–13</sup> Briefly, all of the patients at the TB clinic were asked about their history of DM. Patients not aware of their status were offered random blood glucose (RBG) testing. Venous blood samples were collected from the patients and blood glucose was tested by the hexokinase method. If RBG was  $\geq 110$  mg/dl, the patients were offered fasting blood glucose (FBG) testing. The cut-offs used in the study were as follows: FBG  $< 110$  mg/dl was considered normal; FBG 110–125 mg/dl was diagnosed as pre-diabetes; and FBG  $\geq 126$  mg/dl was diagnosed as DM.<sup>14</sup> Patients with known DM and newly diagnosed DM were

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#### KEY WORDS

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referred to the diabetes clinic for further management. Testing for human immunodeficiency virus (HIV) infection was offered routinely to TB patients; information on HIV status was extracted from the TB registers.

At the DM clinic, patients were asked whether they were under TB treatment. Those who were not were asked about specific symptoms and signs indicative of TB (cough for  $\geq 2$  weeks, prolonged fever, weight loss, loss of appetite, enlarged glands). Patients who gave an affirmative answer for any of these symptoms were referred to the TB clinic for further evaluation. At the TB clinic, these patients underwent investigations including sputum smear microscopy, chest radiography and other investigations per RNTCP guidelines. Type of TB was classified per the national guidelines, which are in line with WHO recommendations.<sup>11</sup>

### Data collection and validation

At the TB clinic, an additional TB-DM register was used to record data on the following variables: age, sex, current smoker (defined as a person who had smoked tobacco at least once during the last 3 months), residence (urban or rural), HIV status, RBG and FBG levels, dates of TB diagnosis, RBG and FBG tests and referral and enrolment into DM care. At the DM clinic, a separate treatment card for each patient was used to record data about the patient's DM history and current DM status, screening for TB symptoms, the result of screening and the result of the investigations. The existing staff of the TB and DM clinics in the routine health care setting were trained and involved in the study; no additional manpower or infrastructure was used. Supervision and site visits were undertaken by staff from The Union and the RNTCP during the study, and all the records were checked for completeness, consistency and accuracy.

### Data analysis and statistics

The individual patient data were double-entered into EpiData software, version 3.1 (EpiData Association, Odense, Denmark), validated and analysed. The data were summarised using frequencies and proportions. Differences between groups were compared using the  $\chi^2$  test. A *P* value of  $<0.05$  was considered statistically significant. The number needed to test (NNT, defined as reciprocal proportion of the sum of new DM and pre-diabetes cases) was calculated, disaggregated by demographic and clinical characteristics.

### Ethics approval

We obtained administrative approval from the head of the Bangalore Medical College and Research Institute, Bangalore. The entire protocol was reviewed and approved by the Ethics Advisory Group of The Union.

## RESULTS

### Screening tuberculosis patients for diabetes mellitus

The results of DM screening among TB patients are summarised in Table 1. The median (interquartile range) age of the TB patients was 35 (25–45) years. Of 510 TB patients, 32 (6.3%) had been previously diagnosed with

**TABLE 1** Screening TB patients for DM at Bowring and Lady Curzon Hospital, Bangalore, India, March–September 2012

Indicator	<i>n</i> (%)
Patients with TB registered over the study period	510
Patients with a known diagnosis of DM	32 (6.3)
Patients needing to be screened with RBG	478
Patients screened with RBG	478 (100)
Patients with RBG $\geq 110$ mg/dl	110
Patients screened with FBG	109 (99.1)
Patients with FBG $<110$	79
Patients with FBG 110–125	15 (2.9)
Patients with FBG $\geq 126$ mg/dl (newly diagnosed with DM)	15 (2.9)
Patients with known or newly diagnosed DM	47 (9.2)
Patients with known and newly diagnosed DM referred to DM care	47 (100)
Patients with known or newly diagnosed DM reaching DM care	45 (95.7)

TB = tuberculosis; DM = diabetes mellitus; RBG = random blood glucose; FBG = fasting blood glucose.

DM. Screening among the remaining 478 patients yielded 15 (2.9%) and 15 (2.9%) pre-diabetes and new DM cases, respectively. Of the 47 known/newly diagnosed patients, 45 (96%) were registered at the DM clinic for further management. Almost all patients underwent RBG testing within one day of the date of TB diagnosis;  $>95\%$  of the patients eligible for FBG underwent the test within 2 days of the RBG test.

The demographic and clinical characteristics of TB patients associated with DM prevalence are shown in Table 2. DM prevalence was significantly higher among

**TABLE 2** Characteristics of TB patients screened for DM at Bowring and Lady Curzon Hospital, Bangalore, India, March–September 2012

Characteristic	Total TB patients <i>n</i>	Patients with DM <i>n</i> (%)	<i>P</i> value
Total	510	47 (9.2)	
Age, years			
$<40$	319	12 (3.8)	$<0.001$
$\geq 40$	191	35 (18.3)	
Sex			0.36
Male	316	32 (10.1)	
Female	194	15 (7.7)	
Residence			0.52
Urban	393	38 (9.7)	
Rural	117	9 (7.7)	
Smoking status*			$<0.001$
Smoker	137	23 (16.8)	
Non-smoker	372	23 (6.2)	
HIV status			0.54
Positive	83	8 (9.6)	
Negative	423	38 (9.0)	
Unknown	4	1 (25.0)	
Type of TB			$<0.001$
Pulmonary	205	30 (14.6)	
Extra-pulmonary	305	17 (5.6)	

\*Not recorded for one TB patient.

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

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**TABLE 3** Number needed to screen to find a new case of DM and pre-diabetes among TB patients at Bowring and Lady Curzon Hospital, Bangalore, India, March–September 2012

Characteristic	A Patients with unknown DM status <i>n</i>	B New DM cases diagnosed <i>n</i>	C Pre-diabetes cases diagnosed <i>n</i>	NNT (A/B+C)
Total TB patients	478	15	15	16
Age, years				
<40	312	5	5	31
≥40	166	10	10	8
Sex				
Male	294	10	11	14
Female	184	5	4	20
Residence				
Urban	367	12	12	15
Rural	111	3	3	18
Smoking status*				
Smoker	122	8	5	9
Non-smoker	355	6	10	22
HIV status				
Positive	77	2	1	25
Negative	397	12	14	15
Unknown	4	1	0	40
Type of TB				
Pulmonary	184	9	8	11
Extra-pulmonary	294	6	7	23

\*Not recorded for one TB patient.

DM = diabetes mellitus; TB = tuberculosis; NNT = number needed to test; HIV = human immunodeficiency virus.

TB patients aged ≥40 years, among smokers, and in patients with pulmonary TB (PTB).

The NNT to find a new case of DM and/or pre-diabetes is summarised in Table 3. The overall NNT in this cohort of TB patients was 16. However, the NNT was lower among TB patients aged ≥40 years, smokers, and individuals with PTB.

### Screening diabetes mellitus patients for tuberculosis

The results of TB screening among DM patients are shown in Table 4. Overall, 1670 DM patients were seen at least once during this period. Of these, 45 were already known TB patients: 17 new smear-positive PTB, 9 new smear-negative PTB, 16 new extra-pulmonary TB, 1 new-others and 2 treatment after default. Of the remaining 1625 patients screened for TB, 152 (9.3%) were found to have symptoms suggestive of TB, and they were referred to the

**TABLE 4** Screening of DM patients for TB at Bowring and Lady Curzon Hospital, Bangalore, India, March–September 2012

Indicator	<i>n</i> (%)
Patients seen in the DM clinic during this period	1670
Patients already diagnosed with TB elsewhere	45
Patients screened at least once for TB symptoms in this period	1625
Of those screened, patients with a positive TB symptom screen	152 (9.3)
Patients with a positive TB symptom screen referred for TB investigations	152
Patients diagnosed with TB after referral for investigations	2 (0.1)
Patients identified with TB (known and new)	47 (2.8)
Patients with TB receiving treatment	47

DM = diabetes mellitus; TB = tuberculosis.

TB clinic for further evaluation. All those referred reached the TB clinic and underwent evaluation. Among the 152 symptomatic patients, two new smear-positive TB patients were diagnosed and initiated on TB treatment. The NNT to detect one person with symptoms suggestive of TB was ~10, and for detection of one TB case it was ~812.

## DISCUSSION

The findings of this study provide important insights into the programme management of TB-DM co-morbidity, and have several health policy implications.

First, we implemented bidirectional screening for TB and DM using existing resources and staff, thus indicating that this is feasible. Almost all TB patients underwent screening for DM and vice versa. One of the primary reasons for the low loss to follow-up was the close proximity of the TB and DM clinics. The process of screening yielded additional new cases of DM and TB, although the NNT to detect one new TB case among DM patients was high compared with the NNT to detect DM among TB patients.

Second, about 10% of TB patients attending the TB clinics had DM. This is lower than the prevalence reported from other sites in South India, where it ranged from 25% to 44%.<sup>8–10</sup> It should be noted that the median age of our study population was lower than that in the other studies, and it is well known that the prevalence of diabetes increases with age. The tests and criteria used for the diagnosis of DM in our study (RBG followed by FBG) differed from those used in other studies.<sup>8–9</sup> The sensitivity of FBG is lower than that of the 75 g oral glucose tolerance test, and this may have resulted in underestimation of the true proportion of DM in our population. Furthermore, the screening yielded 15 patients with pre-diabetes who are at higher risk of developing type 2 DM in the future. These patients could be targeted for counselling and other preventive services. Another reason is probably the higher proportion of extra-pulmonary TB patients observed in our study, who are known to have a lower prevalence of DM.<sup>15</sup>

Third, nearly two thirds of all identified DM patients knew their status prior to screening. This could be because of the nature of the study setting, i.e., a tertiary care hospital where patients have the opportunity to periodically undergo various investigations, including those for DM. Given the ease and speed of performing DM tests, the results are usually available earlier than those for TB tests. This might also have contributed to the higher proportion of previously known DM. Nevertheless, the early identification of patients with co-morbidity, especially among the newly diagnosed cases, helped us to link these patients to appropriate DM care, which could lead to improved TB treatment outcomes.

Fourth, nearly 10% of the DM patients screened (at least once during the study period) in the DM clinics had symptoms suggestive of TB. This is higher than in the general health facility setting, where it is estimated that ~2–3% of patients have TB symptoms.<sup>16–17</sup> However, we found very few TB cases among them. While the exact reasons for the low yield are not clear, it could be due to the fact that DM patients were managed by individual physicians at diagnosis, and only after glycaemic control was achieved were they referred to DM clinic for periodic visits and collection of free drugs. Patients attending DM clinics were therefore more likely to have adequate glycaemic control and could thus have had a lower risk of having TB.<sup>15</sup> The other reason for the low yield could be the lack of availability of state-of-the-art diagnostic tools, such as nucleic acid amplification tests or culture. Future studies should focus on the use of these tools to evaluate whether this could increase the yield of TB among screened DM patients.

One limitation of our study was that we were not able to ascertain whether a high FBG in patients with TB was indicative of true DM or of infection-induced hyperglycaemia. This requires periodic blood glucose testing over the course of TB treatment, which was beyond the scope of the current study. Further research is needed to ascertain this and the optimum timing of DM screening among TB patients. The other related limitation was that we could not use a glycosylated haemoglobin test for the diagnosis of DM, and this might have led to an under-diagnosis of pre-diabetes and DM. However, as the glycosylated haemoglobin test is expensive, its use in programme conditions needs further evaluation.

In conclusion, our study showed that bidirectional screening for DM and TB was feasible, with a high yield of DM among TB patients. Screening TB patients for DM could be an efficient tool for the programme management of TB-DM co-morbidity. The yield of TB among DM patients was low and needs future research using new, improved TB diagnostic tools.

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**Contexte :** Dispensaires de tuberculose (TB) et de diabète (DM) à l'Hôpital Bowring et Lady Curzon, un centre de soins tertiaires à Bangalore, Inde.

**Objectif :** Evaluer la faisabilité et les résultats d'un dépistage bidirectionnel TB-DM.

**Méthodes :** Il s'agit d'une étude descriptive menée entre le 1er mars et le 30 septembre 2012 pendant laquelle les patients TB ont fait l'objet d'une évaluation pour DM et vice versa. Un glucose sanguin à jeun  $\geq 126$  mg/dl et a été considéré comme DM et un glucose sanguin à jeun de 110–125 mg/dl comme prédiabète.

**Résultats :** Sur 510 patients TB, 32 (6,3%) avaient été diagnostiqués antérieurement comme diabétiques. Le dépistage parmi les 478 patients TB restants a eu un rendement de 15 sujets prédiabétiques

(2,9%) et de 15 nouveaux cas de diabète (2,9%). On a trouvé une prévalence plus élevée de DM chez les patients de  $\geq 40$  ans, chez les patients atteints de TB pulmonaire et chez les fumeurs. Sur 47 patients TB-DM, 45 ont été pris en charge pour leur DM. Sur 1670 patients DM suivis dans les dispensaires du DM, 45 avaient déjà une TB. Parmi les 1625 restants et dépistés, 152 (9%) souffraient de symptômes suggestifs de TB, parmi lesquels deux patients souffraient de TB.

**Conclusion :** Le dépistage bidirectionnel pour DM et TB est réalisable et donne un rendement élevé pour le DM chez les patients TB. Le rendement de TB parmi les patients DM est faible et nécessite des recherches ultérieures utilisant des outils améliorés pour le diagnostic de la TB.

**Marco de referencia:** Los consultorios de tuberculosis (TB) y diabetes (DM) en el Hospital Bowring y Lady Curzon, un centro de atención terciaria de Bangalore en la India.

**Objetivo:** Se buscó evaluar la factibilidad del cribado bidireccional de la TB y la DM y los resultados de esta intervención.

**Métodos:** Fue este un estudio descriptivo realizado entre el 1° de marzo y el 30 de septiembre del 2012, en el cual se investigó en todos los pacientes TB el diagnóstico de DM y vice versa. Una glucemia en ayunas igual o superior a 126 mg/dl determinó el diagnóstico de DM y entre 110 y 125 mg/dl definió el diagnóstico de prediabetes.

**Resultados:** De los 510 pacientes con TB, 32 contaban con un diagnóstico previo de DM (6,3%). Con el cribado de los 478 pacientes restantes se estableció el diagnóstico de 15 casos de prediabetes

(2,9%) y de 15 casos nuevos de DM (2,9%). Se observó una prevalencia de DM más alta en los pacientes  $\geq 40$  años de edad, los pacientes con TB pulmonar y los fumadores. Cuarenta y cinco de los 47 pacientes con TB y DM se inscribieron en el programa de atención de la DM. De los 1670 pacientes atendidos en las consultas de DM, en 45 se había establecido ya el diagnóstico de TB. De los 1625 pacientes restantes que participaron en el cribado, 152 presentaban signos indicativos de TB (9 %) y en dos de ellos se confirmó el diagnóstico.

**Conclusión:** La detección sistemática bidireccional de la DM y la TB es factible y ofrece un alto rendimiento diagnóstico de casos de DM en los pacientes que sufren TB. El rendimiento diagnóstico del cribado de la TB en los pacientes DM fue bajo y se precisan nuevas investigaciones que utilicen instrumentos diagnósticos de la TB nuevos y mejorados.