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Screening patients with tuberculosis for diabetes mellitus in Gujarat, India

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Setting: Anklav Tuberculosis Unit, Anand, Gujarat, India.
Objective: To determine in a cohort of TB patients 1) the prevalence of diabetes (DM) and impaired fasting glucose (IFG), 2) the time taken for diagnosis, 3) demographic and clinical factors associated with DM and IFG, and 4) the number needed to screen (NNS) for diagnosing new cases of DM and IFG.
Design: Descriptive study. TB patients registered between January and September 2012 were asked whether they had a history of DM. Those with unknown DM were tested for random and fasting blood glucose (FBG). FBG of ⩾126 mg/dl and 110–125 mg/dl were considered indicative of DM and IFG, respectively.
Results: Of 556 TB patients, 553 (99%) were assessed: 36 (6.5%) had diabetes (14 had been previously diagnosed DM and 22 were newly diagnosed), and 39 (7%) had IFG. The median (interquartile range) time to DM diagnosis was 5 (1–17) days. Age ⩾35 years was associated with DM. The NNS was 25 and 14 for one new case of DM and IFG, respectively, with a lower NNS in males, those aged ⩾35 years, those with smear-positive pulmonary TB, retreatment patients and smokers.
Conclusion: This pilot project shows that it is feasible and valuable to screen patients with TB for DM in a routine setting, resulting in earlier identification of DM and opportunities for better management of comorbidity.

Tuberculosis (TB) continues to be a major health problem in India, with an estimated 3.1 million prevalent cases and an average annual mortality of 0.32 million.[1] This high national burden of TB is made potentially worse by other diseases, such as human immunodeficiency virus/acquired immune-deficiency syndrome (HIV/AIDS), in some districts that can lead to higher rates of disease, increased transmission of infection and poor treatment outcomes.

With India in transition in terms of socio-economic development and lifestyle changes, there is also a rising epidemic of diabetes mellitus (DM). It is estimated that there are over 60 million people currently with DM in the country, and almost half are undiagnosed, with the number expected to increase to 80 million by 2030.[2,3] This increase in the prevalence of DM has been noted in both urban and rural areas. A recent review reported that the prevalence of DM ranged from 3% to 12% across different rural areas of the country, with an expected rate of increase of 2.0 per 1000 population per year.[4]

DM has been shown to be an independent risk factor for TB,[5] and there is evidence showing high DM prevalence in TB patients in community-based studies mainly from the southern part of India.[6–8] DM is said to account for about 10% of the population-attributable fraction of TB cases globally,[9] although this will vary from country to country depending on the degree of overlap between DM and TB in the population. It has been suggested by modelling analysis that DM may account for 15% of all TB and 21% of smear-positive TB cases.[10]

This strong association raises the question as to whether TB patients should be routinely screened for DM. In this regard, a systematic review of screening conducted in multiple settings showed that the yield of DM from screening patients with TB varied from 1.7% to 36%, with this proportion being influenced by the underlying burden of TB and the severity of DM.[11] The presence of concomitant DM amongst TB patients is also associated with a higher risk of poor treatment outcomes in terms of treatment failure, relapse and death.[12] Screening for DM in TB patients could thus potentially identify DM cases early; this might lead to early linkage to DM care,[13] which in turn might improve treatment outcomes.[14]

There has been an international call for investment in collaborative care directed towards TB and DM.[15] Appreciating the need to implement this joint framework in India, a consensus was reached among multiple stakeholders, including the national authorities, to initiate screening for DM among TB patients in pilot settings across India. The results of this countrywide screening have been reported in terms of aggregate data,[13] and this has encouraged the belief that DM screening and care should be integrated into India's Revised National TB Control Programme (RNTCP). We report the implementation findings and lessons learnt in Gujarat, one of the network of pilot sites where the feasibility of and yield from introducing DM screening for TB patients under routine programme settings were assessed. The specific objectives of this study were to determine 1) the prevalence of DM and impaired fasting glucose (IFG) in a cohort of TB patients, 2) the time intervals for the diagnosis of DM and IFG, 3) demographic and disease-related factors associated with DM and IFG, and 4) the number needed to screen (NNS) for diagnosing patients with newly diagnosed DM and IFG.

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METHODS

Study setting and population

Anand, a district in Gujarat State in western India, has a population of 2.1 million. It has 11 community health centres, 43 primary health centres and two tertiary care centres, in the form of one private medical college and one civil hospital. For its TB control activities, the district is covered by the RNTCP, which has been operating since 2004 along the same basic principles as the World Health Organization's (WHO's) DOTS strategy. Under the RNTCP, the district has four Tuberculosis Units (TUs), geographical areas defined as sub-district level programme management units, each covering a population of 250 000–500 000, with TB diagnostic and treatment services being delivered through a network of primary, secondary and tertiary health care facilities. The district also has 23 designated microscopy centres—1 per 0.1 million population—for performing quality assured sputum microscopy, and 33 sputum collection and transportation centres situated in the remotest parts of the district where no other health care facility or easy transport system is available.

In the last 5 years, the district has consistently achieved the twin RNTCP objectives, i.e., treatment success rates of ⩾85% among new smear-positive cases and detection rates of ⩾70% of estimated cases. In 2012, 14 963 patients with presumptive TB were investigated, and 2999 TB patients were placed on standardised treatment.

The implementation site for the current descriptive study was the Anklav TU in the Anand district. This TU covers a population of 0.57 million, 85% of whom live in rural areas. The TU has 16 government health facilities in the form of peripheral health institutions (PHIs), where this project was implemented.

Screening procedures for diabetes mellitus

All health facilities were provided with DM testing kits containing glucometers and test strips. Laboratory technicians were instructed to perform DM screening as soon as a patient was confirmed as having TB. The RNTCP diagnostic algorithm was used for the diagnosis of TB.[16] In some patients where the diagnosis was made through sputum collection centres, screening was performed during outreach sessions ('Mamata Day') organised in the village locally by a laboratory technician. These sessions were held for other primary care activities into which the DM screening activity was integrated to enhance TB screening coverage within the district.

At all sites, patients were first asked whether they had previously been diagnosed with DM. Patients with a previous diagnosis were referred back for DM care so that their blood glucose levels could be controlled. Those with no known diagnosis of DM underwent a random blood glucose (RBG) test based on a capillary blood sample with a glucometer, followed by an FBG test at the next visit if the RBG was ⩾110 mg/dl. The diagnosis of DM followed national guidelines, with FBG cut-off thresholds as recommended by the WHO.[17] Briefly, FBG ⩾126 mg/dl (⩾7 mmol/l) indicates DM; FBG 110–125 mg/dl (6.1–6.9 mmol/l) indicates IFG; and FBG <110 mg/dl (<6.1 mmol/l) is normal.

Provision of care for diabetes mellitus

TB patients with FBG of ⩾126 mg/dl were diagnosed with presumptive DM and referred to the diabetes services in public hospitals with DM facilities for a definitive diagnosis and enrolment in care. Three DM health care facilities are distributed equally within the TU, one of which is at the private medical college.

The state level officer and district TB officer were trained at national level in January 2012, after which district and sub-district level staff were trained using a training module.[18] The DM testing kits were supplied at the end of February 2012.

Study participants

All TB patients (adults and children) registered from January to September 2012 were enrolled into the screening programme. DM screening was initiated in the facilities from 1 March 2012.

Data collection and data variables

An additional TB-DM register was developed and used to capture the screening results. All sites were visited by the study investigators at monthly intervals to check for completeness, consistency and accuracy of data, and any issues relating to recording and reporting were resolved. Variables related to the study objectives were sourced from the TB-DM register and TB register.

Data entry analysis and statistics

All data from the TB-DM register were double entered into an electronic database created using EpiData entry software version 3.1 (EpiData Association, Odense, Denmark), validated for discrepancies and corrected. Additional variables such as age, sex, type of TB and HIV status, were captured in MS Excel® (Microsoft, Palisade Corp, Newfield, NY, USA) and merged into the EpiData database before analysis. The data was analysed using EpiData analysis software (version V2.2.2.180). Statistical differences between patient characteristics among prevalent DM cases and patients with no DM were evaluated using the χ^2 test or Fisher's exact test, as appropriate. Confidence intervals of 95% were used; the level of significance was set at ⩽0.05.

Ethics

Ethics approval was obtained from the Ethics Advisory Group of the International Union Against Tuberculosis and Lung Disease, Paris, France. Programmatic approval was granted for the study at state and national level.

RESULTS

Of the 556 TB patients (median age 35 years, interquartile range [IQR] 25–50 years) registered, the majority were screened for DM (Table 1). Of these patients, 36 (6.5%) were found to have DM: 14 (2.5%) had a previous diagnosis of DM and 22 (4%) were newly diagnosed. The median FBG in newly diagnosed DM patients was 248 mg/dl (IQR 153–337 mg/dl); 39 (7.0%)

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Conflict of interest: none declared.

TABLE 1 Screening of patients with TB for DM in Anklav Tuberculosis Unit, Gujarat, January–September 2012

Indicator	*n*	%
Patients with TB registered over the 3 quarters	556	
Patients with a known diagnosis of DM	14	2.5
Patients needing to be screened with RBG	542	
Patients screened with RBG	539	99.4
Patients with RBG >110 mg/dl, needing to be screened with FBG	229	
Patients screened with FBG	227	99.1
Patients with FBG ⩾126 mg/dl (newly diagnosed with DM)	22	4.1
Patients with FBG ⩾110 to <126 mg/dl (impaired fasting glucose)	39	7.0
Patients with known and newly diagnosed DM	36	6.5
Patients with known and newly diagnosed DM referred for DM care	34	94.4
Patients with known or newly diagnosed DM who reached DM care	32	94.1

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

had IFG. Most DM patients were referred to and enrolled into DM care; no action was taken for patients with IFG. Of the 74 patients with extra-pulmonary TB, 54 had lymphadenopathy, 18 pleural effusion, 1 abdominal TB, 1 bone TB; of these, 3 had DM.

The time intervals between the start of TB treatment and the RBG and FBG measurements are shown in Table 2. The glucometer and test strips were not available in the health care facility, as the National Programme for Prevention and Control of Cancer, Diabetes and Stroke (NPCDCS) had not been implemented in the district; these had to be procured through external sources, and they arrived towards the end of the first quarter. For the two quarters combined, the median (IQR) time interval from TB treatment to DM diagnosis was 5 days (1–17)—with a median of 2 days between TB treatment initiation and RBG, and a further 2 days between RBG and FBG.

TABLE 2 Interval between start of TB treatment and diagnosis of DM in TB patients in Anklav Tuberculosis Unit, Gujarat, January–September 2012

	Quarter 2 duation, days median [IQR]	Quarter 3 duration, days median [IQR]
TB treatment start date to RBG	2 [0–24]	2 [0–7]
RBG to FBG	2 [1–12]	3 [2–5]

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

The number of TB patients with DM and the NNS for diagnosing DM and IFG are shown in Table 3. The only characteristic associated with increased DM prevalence was age ⩾35 years (P = 0.001). There were no characteristics associated with IFG. Among those screened, 18 (3.2%) were children. None of these was diagnosed with DM. The NNS for all TB patients was 25 for one new DM case, and 14 for one new case of IFG. The NNS for identifying a new case of DM was lower in males, those aged ⩾35 years, those with smear-positive pulmonary TB, those on a re-treatment regimen, smokers and those who were HIV-negative. The median age of the HIV-infected subjects was 30 years (IQR 20.5–38.0).

TABLE 3 TB patients NNS to identify new case of DM, one new case with IFG, and both DM and IFG, in Anklav Tuberculosis Unit, Gujarat, January–September 2012

Characteristic	TB patients registered *n*	TB patients with DM *n*	New DM *n*	IFG *n*	NNS for new DM *n*	NNS for new IFG *n*	NNS for both DM and IFG *n*
Total	556	36	22	39	25	14	9
Age, years							
<35	236	4	2	12	118	20	17
⩾35	320	32	20	27	16	12	7
Sex							
Male	371	27	18	25	21	15	9
Female	185	9	4	14	46	13	10
Initial sputum smear result*							
Smear-positive	364	26	17	28	21	13	8
Smear-negative	120	8	4	6	30	20	12
Type of TB†							
New case	429	24	15	34	29	13	9
Retreatment	126	12	7	5	18	25	11
Current smoking status‡							
Current smoker	89	9	9	11	10	8	4
Non-smoker	462	25	13	28	36	17	11
Disease classification							
Pulmonary	482	34	21	36	23	13	8
Extra-pulmonary	74	2	1	3	74	25	19
HIV status							
Negative	532	35	22	38	24	14	9
Positive	24	1	0	1	—	24	24

*Initial sputum results were not recorded for 65 extra-pulmonary TB patients and 7 pulmonary TB patients.
†One transfer-in patient not included.
‡Defined as having smoked tobacco at least once in the last month; data not available for 5 patients.
TB = tuberculosis; NNS = number needed to screen; DM = diabetes mellitus; IFG = impaired fasting glucose; HIV = human immunodeficiency virus.

DISCUSSION

In the setting of a TU in India with a predominantly rural population, screening of TB patients for DM and IFG was feasible, with nearly 100% of patients agreeing to be tested, and over 13% being diagnosed with either DM or IFG. The time from the start of TB treatment to diagnosis was <1 week, which was short, considering that this was a two-step process requiring RBG to identify those at risk and FBG to establish the diagnosis. The baseline characteristic significantly associated with DM was age, with patients aged ⩾35 years having an increased prevalence of disease. No case of DM or IFG was found among children suffering from TB. This suggests that child TB patients do not need to be screened for DM. The NNS to identify one new case of DM was 25, with fewer needed for certain categories of patient, including men, those aged ⩾35 years, those with smear-positive and recurrent disease and smokers.

At 6.5%, the prevalence of DM in TB patients in our TU was low compared with other pilot sites in India.[13] This is probably explained by the fact that our patients came mainly from rural areas, with a relatively low median age. A study in the urban population of Ahmedabad, Gujarat, found a 14% prevalence of type 2 DM and 6% IFG.[19] Due to the young age of the HIV-infected individuals, the incidence of pre-existing DM in this group was relatively low.

There are concerns that TB may induce infection-related hyperglycaemia,[20–22] and that investigations for DM should be conducted later during the course of TB treatment to avoid false-positive diagnoses. In our study, the median FBG in newly diagnosed DM patients was almost 250 mg/dl, which is twice as high as the cut-off threshold. This suggests that even if stress-induced hyperglycaemia is present, it is important to screen early during TB treatment so that appropriate measures can be taken to reduce the high blood glucose levels. A caveat is that we do not currently know whether good blood glucose control early on in the course of TB treatment affects treatment outcomes.

The strengths of this study are that we implemented screening within the routine system with existing staff. Furthermore, with just one day of training, clinical and nursing staff were able to follow the diagnostic algorithm and record appropriate data in the devised formats. There were, however, some challenges. First, as the NPCDCS had not been implemented in the district, the glucometer and test strips had to be procured through external sources. Second, for the same reason, there was no free supply of oral hypoglycaemic drugs, and some patients had to pay for these as out-of-pocket expenses. Third, the fact that it was a rural area meant that only one specialised doctor was available to manage clinically complicated DM-TB patients, and patients needed special counselling to ensure that they visited the specialist for regular follow-up.

In conclusion, this study demonstrates the feasibility and value of screening TB patients for DM in a predominantly rural area. The information from this study is also useful for national scale-up. It shows that simple diagnostic technology should be in place at the start of screening activities, and that DM drugs should be available free of charge for patients to avoid out-of-pocket expenses; both of these issues highlight the importance of scaling up DM screening in parallel with the scale-up of the NPCDCS programme and/or the scale-up of state health systems resources. Our study also indicates the importance of training peripheral health care workers in the simple management of DM so that patients do not have to make long journeys for specialist care and follow-up.

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Contexte : Unité de Tuberculose (TB) d'Anklav, Anand, Gujarat, Inde.
Objectif : Déterminer dans une cohorte de patients TB, 1) la prévalence du diabète (DM) et les détériorations du glucose à jeun (IFG), 2) la durée avant le diagnostic, 3) les facteurs démographiques et cliniques associés à DM et IFG, et 4) le nombre de sujets à dépister (NNS) pour diagnostiquer un nouveau cas de DM et d'IFG.
Schéma : Etude descriptive : on a interrogé les patients TB enregistrés entre janvier et septembre 2012 au sujet d'antécédents de DM. Chez ceux dont le DM n'était pas connu le glucose a été mesuré au hasard et à jeun (FBG). On a considéré respectivement comme DM et IFG un FBG de ⩾126 mg/dl et 110–125 mg/dl.
Résultats : Sur 556 patients TB, 553 (99%) ont fait l'objet d'une évaluation ; 36 (6,5%) souffraient de diabète (14 dont le DM était déjà connu et 22 nouvellement diagnostiqués) et 39 (7%) souffraient d'IFG. La durée médiane (IQR) avant le diagnostic a été de 5 jours (1–17). Un âge ⩾ 35 ans a été en association avec le DM. Le NNS était respectivement de 25 et de 14 pour un nouveau cas de DM et d'IFG, avec un NNS plus faible chez les hommes, dans le groupe d'âge ⩾ 35 ans, dans les TB pulmonaires à frottis positif, chez les patients en retraitement et chez ceux fumant actuellement.
Conclusion : Ce projet pilote démontre qu'il est faisable et valable de dépister le DM chez les patients atteints de TB dans un contexte de routine, ce qui entraine une identification plus précoce du DM et des occasions d'une meilleure prise en charge de cette co-morbidité.

Marco de referencia: La Unidad de Tuberculosis (TB) de Anklav del distrito de Anand, en el estado de Gujarat, en la India.
Objetivo: Determinar en una cohorte de pacientes TB los siguientes aspectos: 1) la prevalencia de diabetes (DM) y alteración de la glucemia en ayunas (IFG, prediabetes), 2) el lapso necesario hasta el diagnóstico, 3) los factores demográficos y clínicos que se asocian con la DM y la IFG, y 4) el número de personas que se deben examinar (NNS) con el fin de diagnosticar un caso nuevo de DM y IFG.
Métodos: Fue este un estudio descriptivo, en el cual se interrogó a los pacientes registrados por TB entre enero y septiembre del 2012 sobre sus antecedentes de DM. A los pacientes que desconocían su situación con respecto a la DM se practicaron pruebas de glucemia casual (RBG) y glucemia en ayunas (FBG). Se consideró como prediabetes una IFG de 110 a 125 mg/dl y se estableció el diagnóstico de DM con una FBG de ⩾126 mg/dl.
Resultados: Se examinaron 553 de los 556 pacientes con TB (99%); se diagnosticó DM en 36 pacientes (6,5%; 14 de ellos conocían el diagnóstico y 22 fueron casos nuevos) y 39 pacientes presentaron una IFG (7%). La mediana del lapso hasta el diagnóstico de DM fue 5 días (IQR a 17). La edad ⩾35 años se asoció con el diagnóstico de DM. El NNS a fin de detectar un caso de DM fue 25 y para un caso de IFG fue 14. Esta cifra fue inferior en los hombres, en las personas ⩾35 años de edad, en los casos de TB con baciloscopia positiva, en los pacientes en retratamiento de la TB y en los fumadores actuales.
Conclusión: El presente proyecto piloto pone en evidencia que es posible y útil practicar una detección sistemática de la TB y la DM en la práctica corriente y que con esta intervención se logra una detección más temprana de la DM y se ofrecen ocasiones de mejorar el tratamiento de esta morbilidad asociada.

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