

Screening of patients with diabetes mellitus for tuberculosis in India

India Diabetes Mellitus – Tuberculosis Study Group*

Abstract

OBJECTIVE To assess the feasibility, results and challenges of screening patients with diabetes mellitus (DM) for tuberculosis (TB) within the healthcare setting of six DM clinics in tertiary hospitals across India.

METHOD Agreement on how to screen, monitor and record the screening was reached in October 2011 at a national stakeholders' meeting, and training was carried out for staff in the six tertiary care facilities in December 2011. Implementation started in the first quarter of 2012, and we report on activities up to 30th September 2012. Patients with DM were screened for TB on each clinic attendance using a symptom-based enquiry, and those with positive symptoms were referred for TB investigations.

RESULTS In the three quarters, 26% of 7218, 52% of 12237 and 48% of 11691 patients with DM were screened for TB. A total of 254 patients were identified with TB, of whom 46% had smear-positive pulmonary disease. There were 18 patients newly diagnosed with TB as a result of screening and referral, with the remainder being patients already diagnosed from elsewhere. TB case rates per 100 000 patients attending the DM clinic each quarter were 859, 956 and 642. Almost 90% of patients with TB were recorded as starting or being on anti-TB treatment. Major implementation challenges related to human resources and recording systems.

CONCLUSION In India, it is feasible to screen patients with DM for TB resulting in high rates of TB detection. More attention to detail, human resource requirements and electronic medical records are needed to improve performance.

keywords tuberculosis, diabetes mellitus, screening, India

Introduction

India is a country with 1.2 billion people (17.5% of the world's population) and is undergoing rapid development and urbanisation. As a consequence of this social and economic development, which is associated with increasing physical inactivity, an unhealthy diet and obesity, there has been an escalating epidemic of diabetes mellitus (DM) (Ramachandran *et al.* 2010; Danaei *et al.* 2011; International Diabetes Federation 2011). In the last 20 years, DM prevalence rates have risen in both urban and rural populations and amongst the poor (Ramachandran *et al.* 2010), and data suggest that in 2011 there were an estimated 61.3 million adults with DM, giving a national adult prevalence of 8.3% in persons aged 20 years and older. A further 77 million people were estimated to have had impaired glucose tolerance. In about 50% of these persons, DM or impaired glucose tolerance is undiagnosed (International Diabetes Federation 2011). In terms of absolute numbers and given the size of the

population, this makes India one of the highest DM burden countries in the world.

Diabetes mellitus is a well-known risk factor for the development of active TB, increasing the risk by a factor of 2–3 (Stevenson *et al.* 2007; Jeon & Murray 2008; Dooley & Chaisson 2009; Ruslami *et al.* 2010). Patients with TB who have DM also have worse TB treatment than those who do not have DM, which includes delayed conversion from positive to negative sputum cultures, higher risk of death during TB treatment and higher risk of recurrent disease after treatment has been successfully completed (Baker *et al.* 2011).

Although India has an excellent national TB control programme and follows the 'DOTS' model for TB control, the disease is still a considerable problem, and in 2011, there were an estimated 2.2 million incident cases of TB (range 2.0–2.5 million) with case detection rates of just under 60% (World Health Organization 2012). Screening persons with DM for TB could be one of the strategies for early and increased TB case detection in this setting. Given the high burden of both diseases in India and the known association between DM and TB

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(Balakrishnan *et al.* 2012; Viswanathan *et al.* 2012), patients with DM would merit being screened for TB. In 2011, WHO and the International Union Against Tuberculosis and Lung Disease (The Union) launched a new 'Collaborative Framework for the care and control of Diabetes and Tuberculosis', with one of the important activities being the routine implementation of bidirectional screening of the two diseases (World Health Organization & The International Union Against Tuberculosis & Lung Disease 2011). However, ways of screening, recording and reporting for the two diseases in routine healthcare settings are not well determined (Harries *et al.* 2010a; Jeon *et al.* 2010).

In India, a standardised procedure of screening patients with DM for TB, a monitoring tool and a quarterly system of reporting were developed for piloting and agreed upon in the last quarter of 2011. Implementation started in the first quarter of 2012. This study describes the implementation, results and challenges of screening patients with DM for TB within tertiary healthcare settings across six sites in India.

Methods

Design

This was a prospective observational implementation project in six DM clinics within tertiary healthcare facilities in India. The project design was similar to that used in China (Lin *et al.* 2012).

Setting, sites and background to the project

With support from the World Diabetes Foundation (WDF), a national stakeholders meeting was held in Delhi, India, in October 2011, between the national programme managers of the Revised National Tuberculosis Control Programme (RNTCP) and National Programme for prevention and control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS), national experts in the field of TB and Diabetes, The Union, WHO and WDF to review and discuss linkages between DM and TB, the WHO-Union Collaborative Framework and the need for bidirectional screening. Broad guidelines for how the screening should be carried out were worked out and agreed upon. For project implementation, six health facilities for screening patients with DM for TB were purposively selected based on broad geographical coverage, co-located DM and TB diagnostic facilities and willingness of the staff of these clinics to participate in the project without any further financial resources. Figure 1 shows the geographical distribution of these facilities,

with hospital details and the sites to which patients with presumptive TB were referred and the start date of project implementation shown in Table 1.

In December 2011, a workshop was held with healthcare staff from the six facilities and RNTCP programme managers for developing procedures for screening and referral of patients and monitoring and reporting of data based on the RNTCP guidelines. Treatment cards and cohort reporting forms were developed, printed and distributed to the facilities, and in-service training for staff working in the clinics was carried out. Implementation of activities started during the first or second quarter of 2012. It was agreed that data would be reported in quarterly (Q) cohorts: Q1-2012 (January to March); Q2-2012 (April to June); and Q3-2012 (July to September), and that implementers would convene in October–November 2012 to discuss results, challenges and ways forward.

Patients

Patients were persons aged 15 years and older who had been diagnosed with DM and who were receiving care and treatment in the six DM clinics from the first or second quarter of 2012 up to 30 September 2012.

TB screening, referral, diagnosis and treatment

The screening for active TB followed the RNTCP guidelines, which are based on WHO guidelines on how to identify suspected active TB amongst persons seeking care (Central Tuberculosis Division 2005; World Health Organization 2009). Screening was expected to be carried out every time the patient visited the DM clinic. Patients were asked whether they were on TB treatment, and if not, they were asked about cough for longer than 2 weeks or any suspicion of active TB to account for extra-pulmonary TB (such as fever, weight loss, loss of appetite, presence of enlarged lymph glands). Patients with a positive answer to one or both of these two screening questions were referred to TB services for investigation in accordance with the Operational Guidelines stipulated by the RNTCP. In brief, sputum smear microscopy for acid-fast bacilli was performed followed by chest radiography in those with negative sputum smears for suspected pulmonary disease, and appropriate investigations were carried out for suspected extra-pulmonary disease. More sophisticated investigations such as mycobacterial culture or nucleic acid amplification were not used. When active TB was diagnosed, the patient was referred for TB treatment. Whether TB was diagnosed or excluded, patients were expected to be referred back to the DM clinic for continued care of their DM disease.



Figure 1 Map of India with states and sites where tuberculosis (TB) screening of patients with diabetes mellitus (DM) took place. MVH, MV Hospital for Diabetes and Prof. M Viswanathan Diabetes Research Centre; SRMCRI, Sri Ramachandra Medical College and Research Institute; BLCH, Bowring & Lady Curzon Hospital, Bangalore Medical College & Research Institute; IID, Indian Institute of Diabetes; AIIMS, All India Institute of Medical Sciences; KLES, KLES Dr. Prabhakar Kore Hospital & Medical Research Center.

Monitoring, recording and reporting

A DM treatment card (Figure 2) was developed for recording data about the patient's DM history and current DM status, and every time the patient came to the clinic whether screening for TB symptoms had been carried out, the results of the screening and the results of investigations if the symptom screen was positive. Patients were given a unique identification number, and through this number, the treatment cards were traced back during the subsequent visits.

Standardised quarterly report forms were developed, and these were completed with quarterly data by health clinic staff within 30 days after the end of the quarter to allow for the collection of data from TB Clinics. This quarterly report comprised of information on the cumulative number of patients ever registered in the diabetes clinics up to the end of the quarter (if available), number of patients who visited the clinic at least once during the

quarter, the number screened for TB, number with already known TB diagnosed elsewhere, number with TB symptoms and, of these, the number of patients in whom a new diagnosis of TB was made. The numbers were included in the quarterly reports only if there was documentation of diagnosis. These reports were kept at the facilities and also sent to Central TB Division [The Office of the National Programme Manager of the RNTCP] and The Union's South-East Asia Regional Office located at New Delhi for collation. Supervision and site visits were undertaken by staff of The Union Office and the RNTCP during the study to check on adherence to agreed standardised protocols and to ensure the systematic collection of patient data.

Data analysis and statistics

Quarterly reports were received and cross-checked by staff of the Central TB Division and The Union

Table 1 Characteristics of hospitals which implemented screening of patients with DM for TB in India, 2012

Name of the health facility	City	State	Approximate number of diabetes patients in a week	Number of doctors at diabetes clinics	To where presumptive TB cases were referred	Distance to the nearest TB Clinic	Project start date in 2012
MVH	Chennai	Tamil Nadu	900	8	Same hospital or nearest DMC	1.5 Km	21st March
SRM/CRI	Chennai	Tamil Nadu	150*	4	DMC in the same hospital	NA	1st April
BLCH	Bangalore	Karnataka	150*	5	DMC in the same hospital	NA	1st March
IID	Trivandrum	Kerala	330	6	Nearest DMC	0.5 Km	16th March
AIIMS	Delhi	Delhi	400*	8	DMC in the same hospital	0.25 Km	2nd May
KLES	Belgaum	Karnataka	400	5	DMC in the same hospital	NA	1st February

MVH, MV Hospital for Diabetes and Prof. M Viswanathan Diabetes Research Centre; SRM/CRI, Sri Ramachandra Medical College and Research Institute; BLCH, Bowring & Lady Curzon Hospital, Bangalore Medical College & Research Institute; IID, Indian Institute of Diabetes; AIIMS, All India Institute of Medical Sciences; KLES, KLES Dr. Prabhakar Kore Hospital & Medical Research Center.

DMC, Designated Microscopy Centre run by Revised National Tuberculosis Control Programme (RNTCP).

NA, not applicable; TB, tuberculosis; DM, diabetes mellitus; KM, kilometres.

*Only one medical unit participated in the study.

South-East Asia Regional Office, compiled in Microsoft EXCEL file and then analysed. The number of TB cases per 100 000 persons seen in the DM clinics per quarter was calculated to express TB case rates per 100 000 people screened.

Ethics approval

This was a pilot project aiming to test the feasibility of the TB screening approach amongst patients with DM with a view to learning lessons for national scale-up. As such, formal ethics approval in India was deemed not to be necessary, although facility approval and in some cases local ethical approval were obtained. Permission to use, report and publish the collected data was obtained from The Union Ethics Advisory Group, Paris, France.

Results

Results for TB screening in all six facilities combined for quarter 1, 2012, quarter 2, 2012 and quarter 3, 2012 are shown in Table 2. In the first quarter, only about a fourth of the patients with DM were screened for TB symptoms, and of those with symptoms, just over half were referred for investigation of TB. Only two patients were newly diagnosed with TB. However, nearly 60 patients were identified with TB that had already been diagnosed elsewhere. In the second and third quarters, there was considerable improvement in the screening procedures: about half of the patients were screened for TB symptoms, and of those with positive symptoms 95% or more were referred for TB investigations resulting in 16 patients with newly diagnosed TB. As in the first quarter, a large number of patients in each quarter (74 and 48 respectively) were identified with TB which had been already diagnosed elsewhere. Of the diagnosed and identified patients, 226 (89%) were known to have started or to be on TB treatment.

The number of TB cases (known and newly diagnosed) per 100 000 patients with DM was calculated for each quarter with the denominator being the number of patients with DM who were seen in the clinic in each quarter (Table 2). For the three quarters, there were 18 patients newly diagnosed with TB. In terms of newly diagnosed TB case rates per 100 000 persons actively screened with symptom-based enquiry, the numbers were 105 for the first quarter, 172 for the second quarter and 88 for the third quarter.

The types and category of TB diagnosed and identified during the whole study period are shown in Table 3. The majority of patients had new TB. Of those, the majority had smear-positive pulmonary TB, with smear-negative

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Diabetes Registration Number _____

DIABETES TREATMENT CARD AND TUBERCULOSIS SCREENING: YEAR _____

Name _____ Age _____ Sex _____

Date of diagnosis of DM _____ Type of DM _____ Current Medication _____

Quarter	Month	Date	Weight Kg	Blood Glucose (F,R,PP)*	Outcome **	Medication ***	TB Screen done **** (Y/N)	Positive TB Screen **** (Y/N)	Referred for TB tests (Y/N)	Diagnosed with TB (Y/N)	TB details
Q1	Jan										Date diagnosis
	Feb										
	Mar										
Q2	Apr										TB – type and category
	May										
	Jun										
Q3	Jul										TB Register no.
	Aug										
	Sep										
Q4	Oct										Date TB treatment
	Nov										
	Dec										

* F = fasting; R = random; PP = post-prandial

** Outcome: A = alive in care; DIED – dead; LTFU – lost to follow up; TO = transferred out

*** Medication: Diet: Oral: Insulin

**** TB Screen = asking about cough > 2 weeks and/or suspicion of TB – Positive TB Screen = cough > 2 weeks and/or suspicion of TB

Figure 2 Treatment Card used for screening patients with Diabetes for active tuberculosis (TB).

* F, fasting; R, random; PP, post-prandial. ** Outcome: A, alive in care; DIED, dead; LTFU, lost to follow-up; TO, transferred out.

*** Medication: Diet: Oral: Insulin. **** TB Screen, asking about cough \geq 2 weeks and/or suspicion of TB – Positive TB Screen, cough \geq 2 weeks and/or suspicion of TB.

pulmonary TB and extra-pulmonary TB disease accounting almost equally for the remainder. In 10% of cases, there was no record about the type or category of TB.

The challenges with implementation are shown in Box 1. The two main challenges, especially with the sites seeing large numbers of patients, were human resources and recording and reporting of cases (preparation and update of treatment cards and preparation of quarterly reports). Two sites had a DM registration system where the number of patients ever registered in the clinic was known, but the other sites did not have this system, thus preventing the collation of a total denominator for the study.

Discussion

This is the first national report from India assessing the feasibility, results and challenges of routinely screening patients with DM for TB. In the first quarter, a small proportion of patients were screened for TB, as some sites only started halfway through the quarter, and just over half the patients with a positive symptom screen were referred for TB investigations. However, during the next two quarters, performance improved, and over half

of the nearly 10 000 patients with DM seen per quarter at the clinics were screened for TB; 95% or more of those with positive symptoms were referred for TB investigations. These findings are similar to what was observed in China (Lin *et al.* 2012), where performance was poor at the start but improved as time went on.

More than 250 patients were newly diagnosed or identified with TB during the study period, giving TB case rates for patients with DM attending the clinic that were several orders higher than that reported nationally from the RNTCP (the TB case notification rate per 100 000 for all types of TB in 2011 was 107 [World Health Organization 2012]). It is important to note, though, that more formal direct comparisons of TB case rates in patients with DM with these national figures are not appropriate because denominators, time periods and ways of screening are different.

The patients with TB identified in this study were in two groups. The first and commonest group consisted of patients whose TB had been diagnosed elsewhere and who had started treatment already. This is probably due to the excellent geographical coverage of the TB control programme in India with recent attention paid to univer-

A. Kumar *et al.* **Screening DM patients for TB****Table 2** Screening of diabetes patients for tuberculosis during each quarter for all the sites combined, India, 2012

Indicator	Q1-2012	Q2-2012	Q3-2012
Number of patients with DM seen in the clinic in each quarter	7218	12237	11691
Number of patients with DM already diagnosed with TB from elsewhere	58	74	48
Number (%) of patients with DM screened at least once for TB symptoms in each quarter	1907 (26%)	6393 (52%)	5661 (48%)
Of those screened, number (%) of patients with DM with a positive TB symptom screen	104 (5%)	135 (2%)	160 (3%)
Of those with a positive screen, number (%) of patients with DM referred for TB investigations	57 (55%)	128 (95%)	158 (99%)
Number of patients with DM diagnosed with a new episode of TB after referral for investigations	2	11	5
Total number of patients with DM newly diagnosed TB and already known to have TB*	62*	117*	75*
Number of patients known to have started or to be on anti-TB Treatment	61	99	66
TB cases per 100 000 patients with DM seen in the clinic each quarter	859	956	642

Q, quarter; DM, diabetes mellitus; TB, tuberculosis; PTB, pulmonary tuberculosis; EPTB, extra-pulmonary tuberculosis.

*Total number does not add up to sum of new and known: this is because one site did not have information on the divide of new and known TB cases.

Table 3 Types of TB diagnosed or identified in patients with DM seen in the clinics during the study period, India, 2012

Type and category of TB	Number (%)
All TB	254
New TB	226 (89)
Smear-positive pulmonary TB	114 (50)
Smear-negative pulmonary TB	59 (26)
Extra-pulmonary TB	52 (24)
Other	1 (<1)
Previously Treated TB	3 (1)
Relapse	1
Treatment after default	2
Not recorded	25 (10)

TB, Tuberculosis.

sal access to TB case finding in the community (Sachdeva *et al.* 2012) and is in contrast to the experience in China, where a relatively higher proportion of TB patients were detected as a result of referral from the diabetes clinics.

We think it is fully justified to include these patients in the screening programme outputs because they were TB cases identified during the quarter as a result of systematic enquiry. Knowledge about the TB status of these patients is important so that attentive efforts can be made by physicians to control blood glucose levels. The high proportion of these previously diagnosed patients with TB identified in the screening programme also reflects the wide coverage and population access of TB diagnostic services at the community level in India, either from the RNTCP or from the private sector (Kamineni *et al.* 2011; Satyanarayana *et al.* 2011). Patients are often

investigated simultaneously for both TB and diabetes in these clinics and by the time people are registered for the care of their DM, their TB would already have been diagnosed and therefore recorded as 'previously known TB'. This may be the reason why far fewer patients were newly diagnosed through the screening services offered at the DM clinic (most being diagnosed earlier and elsewhere).

In this study, screening for TB followed the national guidelines for screening and diagnosing TB, which are based largely on sputum smear microscopy and chest radiography (Central Tuberculosis Division 2005). While this has been the mainstay of TB diagnosis in the world for many years, it is time-consuming, costly for the patient who needs to make multiple journeys to the clinic and diagnostically insensitive (Lawn & Zumla 2011). Operational research is clearly needed here to determine whether the new nucleic acid amplification tests such as Xpert MTB/RIF (Cepheid, Inc., Sunnyvale, CA, USA) are cost-effective.

The majority of patients with TB had new, smear-positive pulmonary TB, the most infectious form of tuberculosis, a further reason for identifying them, ensuring they get on to treatment and thus are prevented from transmitting the infection to others, including patients attending the DM clinics. The results of this study show that about 90% of patients were known to be on treatment in the quarter reported. For the remainder, we have no information, but as initial loss to follow-up of diagnosed patients with TB is generally low in India (Sai Babu *et al.* 2008), this may just reflect a deficiency in recording of treatment status in the DM clinics.

Box 1: Key challenges in screening persons with diabetes mellitus for tuberculosis, India, 2012**Human resources issues**

- No special or additional staff were assigned for diabetic clinics; manual recording and reporting of TB screening were additional works.

Patient flow issues

- Multiple visits by patients with DM during a quarter, and therefore a danger of duplicate counting of patients in cohort denominators.
- Reluctance of patients to submit sputum specimens for TB diagnosis in some sites.
- Collection of two sputum specimens on different days was inconvenient for some patients (as this requires additional visits), and several patients were either lost to follow-up or submitted the two specimens on the same day 1 h apart.

Screening and referral issues

- Multiple physicians provided care for patients with DM, but only a few were involved in the pilot project.

Recording and reporting issues

- Most sites had no existing electronic filing system: cards had to be clipped to patient case sheets, and the retrieval of data for reports and cross-verification was difficult.
- Deficiencies in the design of the study recording format – there was no option for recording those who already had TB at the time of screening.

There were two main challenges identified in the screening of patients with DM for TB. First, human resources were an important issue, with almost all the clinics feeling that there was too much pressure with patient loads to add in extra work related to documenting the screening for TB. In China (Lin *et al.* 2012), the clinic with a superlative performance was the one with special staff assigned to screening, special staff designated for recording of data, clear roles and responsibilities outlined and easy access geographically to TB services, and these lessons need to be taken on board if screening performances are to improve.

Second, most sites did not know the number of patients with DM ever registered. The monitoring system could capture the number of patients with DM attending

the clinic each quarter, and in many cases, it is likely that these were the same patients who attended the clinic in the previous quarters. However, because there was no formal registration of patients as occurs in TB or HIV/AIDS programmes (Libamba *et al.* 2005), the cumulative number of patients ever registered, and which increased each quarter as new patients were added to the pool, was not known for all the sites. Hence, it was not possible in this study to get the denominator for DM patients; hence, we used patients with DM attending the clinic each quarter to calculate case rates per quarter. This reflects a general lack of structured recording and reporting for monitoring non-communicable diseases in the country and this deficiency needs to be addressed. The answer to this conundrum, which would lead to duplicate counting of patients, probably lies in real-time electronic medical record systems, which facilitate quarterly cohort reporting of patients with DM attending either hospital clinics in Africa (Allain *et al.* 2011) or primary healthcare centres in the Near East (Khader *et al.* 2012).

The strengths of this study are that we implemented screening within the routine system with no special budget allocated to support these activities. Thus, as was the case in China (Lin *et al.* 2012), decisions to continue or to expand depend entirely on the benefits perceived for patients and public health. We think that because of their higher risk of TB and the fact that patients with DM are anyway more likely to attend health facilities, the marginal costs for TB screening using a symptom-based approach are likely to be small and to prove cost-effective in countries with a high double burden of disease such as India.

Limitations of this study relate to the operational nature of the pilot project and the difficulty in calculating the true TB case notification rates amongst patients with DM. There were problems in determining both numerator and denominator for TB case notification rates. Because most of the sites did not maintain records of dates of diagnosis of previously known TB cases, there were problems in determining the numerator. This was a design flaw in that the format of the treatment record card did not have a column for patients already diagnosed with TB, and, although this information was picked up, it was recorded outside of the treatment card during the current study. The inability of most of the sites to record the unique registration number of individual patients made it challenging to calculate the denominator. This area requires more formal and systematic research. Further work is also needed to better characterise patients with DM at higher risk of TB, and this information might be useful if a more targeted approach to screening is deemed useful.

Conclusion

This study in India shows that it is feasible to screen patients with DM for TB in the routine system leading to TB case rates that are several times higher than that reported at national level in the general population. However, there is a need for better performance, and this requires more attention to detail, a consideration of additional staff to assist with the workload and possibly electronic medical record systems to enable easier cohort reporting.

Screening for active TB in DM clinics should lead to earlier detection of TB (which will help to reduce the risk of nosocomial TB transmission in DM clinics) and earlier and better treatment for TB (which should lead to better outcomes). Finally, non-communicable disease programmes need to work out how best to monitor, record and report on case numbers and their outcomes, so that progress towards the NCD target of reducing deaths by 25% by 2025 in persons aged 30–70 years can be measured (Beaglehole *et al.* 2012).

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