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Original Research Article

Bi-directional screening of tuberculosis patients for type 2 diabetes mellitus and diabetes patients for tuberculosis in Bhubaneswar, Odisha

Shritam Das, Elina Das, Kashyap Bhuyan, Biswajita Prusty, Minaketan Barik, V. S. Yadav, Tahziba Hussain*

Regional Medical Research Centre, Bhubaneswar, Odisha, India

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***Correspondence:**
Dr. Tahziba Hussain,
E-mail: tahziba_hussain@hotmail.com

ABSTRACT

Background: The aim of the study was to assess the feasibility and results of screening diabetes mellitus (DM) patients for tuberculosis (TB) and TB patients for DM within the routine health care settings.
Methods: Prospective observational study was carried out within the Diabetes Centre and TB division from June, 2014 to June, 2016. The screening for active TB in DM and DM in TB patients is followed as per the guidelines of the revised national tuberculosis control programme and national programmes in India.
Results: 350 patients with active TB disease were screened for diabetes during the study period. Among the TB patients, 28% patients were having pre-diabetes and 17% patients were having diabetes. Both the conditions, pre-Diabetes or diabetes, were more common among males, married patients, advancing age, having less education, no specific job, sedentary life style, smoking / drinking, living in crowded areas, poor living conditions as well as unhygienic environment. 350 patients with diabetes were screened for TB in which 8 (2.2%) patients found to have TB. The various socio-demographic factors appeared to be significant factors. RBG levels, cholesterol and triglycerides were raised among most of the diabetes patients. Age, male gender and Cat-I status appeared to be significant factors among patients having both conditions The incidence of TB among T2DM patients is less than that reported from other regions.
Conclusions: Bi-directional screening of TB patients for DM and DM patients for active TB leads to earlier detection of DM as well as TB, better TB-specific treatment, favourable outcome for TB as well as DM and prevention of DM complications. This study is the first of its kind in this State.

Keywords: Bi-directional screening, Tuberculosis, Type 2 diabetes mellitus, Bhubaneswar, Odisha

INTRODUCTION

Type 2 diabetes mellitus (T2DM) has assumed pandemic proportions and is indeed the scourge of the modern era. At present, there are 300 million diabetics worldwide and the number is expected to double over the next five years.[1] 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. India with its huge diabetic population holds the distinction of being dubbed the Diabetic Capital of the world, with 63 million diabetics. India has the largest number of tuberculosis (TB) cases and also the largest number of dually infected individuals, in the world.[2,3] The association between T2DM and TB and their synergistic role in causing human disease has been recognised for centuries.[4-6]

About 10% of TB cases globally are linked to diabetes. The association between T2DM and TB is a challenge for global tuberculosis control. Improved understanding of the bi-directional relationship of the two diseases is necessary for proper planning and collaboration to reduce the dual burden of diabetes and TB.[7-9] In people with TB, it may be appropriate to actively screen for DM. Prevention, screening, and treatment of both diseases together is more effective. Recognizing the serious threat posed by Diabetes-TB, The Revised National Tuberculosis Control Program (RNTCP) calls for strengthening collaboration between TB and Diabetes control programs for better management of Diabetic patients with TB and TB patients with Diabetes.[10]

In this study, we carried out bi-directional screening of TB patients and patients with DM attending the Capital Hospital in Bhubaneswar for estimating the prevalence of Diabetes and TB and determining the risk factors and challenges.

METHODS

Study design and study period

This was a prospective observational pilot study conducted from June, 2014 to June, 2016 carried out in hospital within the routine health services. The study design was similar to that used in other studies.[11,12]

Patients

Blood samples for screening were collected from adults willing to participate in the study. All TB patients who have been consecutively diagnosed and registered under RNTCP were screened for Diabetes. This included patients with new and previously treated TB, smear-positive and smear-negative pulmonary TB and extra-pulmonary TB. The patients who had completed treatment were excluded. Patients with T2DM attending the Diabetes Unit of the hospital were also enrolled in the study, simultaneously.

Screening procedure and diagnosis of diabetes

The screening for DM was followed according to the revised national tuberculosis control programme (RNTCP) and national programme for prevention and control of cancer, diabetes, cardiovascular diseases and stroke (NPCDCS) in India guidelines.[13] The procedures have been described in detail elsewhere.[14]

Diagnostic criteria for diabetes

Diabetes was classified using fasting blood (or plasma) glucose (FBG) levels, the criteria being FBG levels ≥126mg/dl for Diabetes or a self-reported history of taking anti-diabetic drugs after diagnosis by a medical professional in accordance with stipulated guidelines.[15,16]

Diagnostic criteria for Cat-I and Cat-II

Based on the nature/severity of the disease and the patient's exposure to previous anti-tubercular treatments, RNTCP classifies TB patients into two treatment categories, category (Cat)-I and category (Cat)-II. Cat-1 includes patients with newly diagnosed sputum positive and sputum negative pulmonary TB, cases with extensive parenchymal involvement and severe form of extra-pulmonary TB whereas Cat-2 includes sputum smear-positive treatment failure cases, relapse cases and return after interruption.[3] Details about category of treatment, i.e., Cat-I or Cat-II and sputum status at the time of diagnosis, i.e., sputum positive, Sputum negative or extra-pulmonary TB were noted from the TB treatment card.

Data analysis and statistics

SPSS version 16.0 was used for statistical analysis. Prevalences are reported with 95% confidence intervals calculated considering the design effect. Mean and standard deviation for continuous variables and proportions for categorical variables are reported. All variables were described as proportions, and differences between groups were compared for statistical significance using the Chi-Square ($\chi 2$) test and t test, as applicable. P values of <0.05 were considered statistically significant.

In all, 350 patients with active TB disease, registered in RNTCP, attending the OPD of Capital Hospital in Bhubaneswar were enrolled after taking informed consent. The socio-demographic and clinical profile like age, gender, marital status, literacy status, profession, life style (sedentary/active), habits (alcohol/smoking), locality, type of TB, index of sputum positivity, status and period of treatment, blood glucose levels (fasting/random), complications at the time of testing, etc. were documented using standardized questionnaires and analyzed in the context of symptoms at the time testing. They were screened for random blood glucose (RBG) levels by finger prick method using a glucometer (glucocard 01-mini, blood glucose monitoring kit, Arkay factory, inc., Koka-Shi, Shiga, Japan). Only those patients having higher values were selected and advised to return to the clinic next day and/or next visit in a fasting state and a repeat test was carried out for fasting blood glucose (FBG) levels.

At the diabetes Unit of the same hospital, 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. Socio-demographic and clinical data were collected from all patients with

diabetes using standardized forms. Clinical evaluation of each patient included a detailed history of duration and chronology of chest symptoms like cough, dyspnoea, fever, chest pain, and haemoptysis. Additional symptoms such as weight loss, night sweats, tiredness, and loss of appetite or any other presenting complaints of the patient were also noted.

RESULTS

Screening tuberculosis patients for diabetes mellitus

Out of 350 TB patients, 17% (61) were having diabetes and 28% were having pre-diabetes (Table 1).

Table 1: Depicts the number of TB patients diagnosed with T2DM.

Number of TB patients screened (350)	
Type 2 diabetes mellitus	61 (17.42%)
Pre-diabetes	98 (28%)

Table 2: Depicts the socio-demographic and clinical profile of TB patients.

Parameters		Numbers screened (n =350)	Diabetes n (%) [n =61, 17.42]	Statistical analysis χ2, p value
Socio-demographic profile				
Gender	Male	256	46 (17.96)	χ2 =0.79, p=0.78
	Female	94	15 (15.95)	
Age group (in years)	16-30	114	7 (6.14)	χ2 =28.73, p<0.0001
	31-45	129	18 (13.95)	
	46-60	107	36 (33.64)	
Marital status	Married	265	54 (20.37)	χ2 =0.26, p=0.61
	Unmarried	85	7 (8.23)	
Literacy status	Illiterate	141	22 (15.60)	χ2 =0.84, p=0.66
	5-10th class	157	28 (17.83)	
	Graduation	52	11 (21.15)	
Occupation	Unemployed	16	4 (25)	χ2 =20.13, p=0.003
	Regular job	36	12(33.33)	
	labourers	69	4 (5.79)	
	Business	50	16 (32)	
	Housewife	54	8 (14.81)	
	No specified job / others / students	92	11 (11.95)	
	Farmer	33	6 (18.18)	
Habits	Smoking	28	6 (21.42)	χ2 =0.88, p=0.73
	Alcohol	17	2 (11.76)	
	Gutka/Tobacco	53	9 (16.98)	
	All	119	20 (16.80)	
	None	133	24 (18.04)	
Life style	Sedentary	153	29 (18.95)	χ2 =0.27, p=0.60
	Active	197	32 (16.24)	
Locality	Urban slums	152	24 (15.78)	χ2 =3.23, p=0.20
	Housing Colonies	91	21 (23.07)	
	Rural	107	15 (14.01)	
Clinical profile				
Type of TB	Pulmonary	307	50 (16.28)	χ2 =1.66, p=0.20
	Extra-pulmonary	43	11 (25.58)	
Category of treatment	Cat-I	236	45 (19.06)	χ2 =1.03, p=0.31
	Cat-II	114	16 (14.03)	
Bacillary index (sputum positivity)	1+	137	20 (14.59)	χ2 =4.89, p=0.03
	2+	71	7 (9.85)	
	3+	69	16 (23.18)	
	-ve	73	18 (24.65)	

Table 3: Depicts the diagnostic status of TB patients having pre-diabetes and diabetes.

Diabetes (n =61)	n (%)	Statistical analysis, $\chi 2$, p value
Newly diagnosed diabetes	08 (13.11)	χ^2 =31.74, p<0.0001
Established diabetes	53 (86.88)	

Table 2 shows the socio-demographic and clinical profile of TB patients. In all, 73% male and 26% female patients were enrolled in the study. Although there is gender bias in patients attending the RNTCP centres, 17% of males and 15% females were having diabetes. 33% people in the age group 46-60 years, 20% of married patients, 5% of laborers or those having no specified jobs were having diabetes. Among the illiterate TB patients and those having less education, the prevalence of diabetes were similar (15%-17%). Analyzing the risk factors, 34% of TB patients were having habits of all types, namely chewing gutka/tobacco, smoking and alcohol. 16% with diabetes were having all types of habits whereas 38% of TB patients denied of having any such addictive habits. More patients with diabetes were found to be addicted to smoking, drinking alcohol and/or chewing tobacco / gutka. The exact number of people physiologically addicted to smoking and / or drinking could not be estimated. 18% of sedentary patients, i.e., those not involved in activity and 16% of patients having an active life style were having diabetes. This shows that gender, marital status, literacy status, occupation and habits do not appear to be a significant factor whereas advancing age and life style were significant factors (p<0.001) in our study. The mean BMI of TB patients was 17 and patients with diabetes was 19.15. It was observed that 23% of the patients residing in housing colonies were having diabetes whereas the prevalence of diabetes is similar among those living in urban slums and rural areas. 87% of patients were having pulmonary TB whereas 12% were having extra-pulmonary TB. 16% of pulmonary TB patients, 14% of patients with diabetes were having 1+ sputum status. Our study indicated that more patients with diabetes (19%) were taking Cat I type of treatment. Further, 13% were newly diagnosed diabetes (Table 3).

Table 4: Depicts the socio-demographic profile of patients with T2DM (n=350).

Parameters		**No. of patients** [n (%)]	Statistical analysis, $\chi 2$, p value
Age (in years)	<40	59 (16.85)	χ^2 =60.97,
	41 – 50	101 (28.85)	p<0.0001
	51 – 60	98 (28)	
	61 – 70	71 (20.28)	
	>71	21 (6)	
Gender	Male	264 (75.42)	χ^2 =89.52
	Female	86 (24.57)	p<0.0001
Marital status	Married	343 (98)	χ^2=320.64
	Unmarried	7 (2)	p<0.0001
Literacy status	Illiterate	35 (10)	χ^2 =162.78
	Primary school	25 (7.14)	p<0.0001
	Secondary school	123 (35.14)	
	College & above	167 (47.71)	
Occupation	Regular job	123 (35.14)	χ^2 =125.92
	Retired	32 (9.14)	p<0.0001
	Business	66 (18.85)	
	House wife	74 (21.14)	
	Students, others, labourer, etc.	39 (11.14)	
	Nothing	16 (4.57)	
Life Style	Active	121 (34.57)	χ^2 =32.72
	Sedentary	229 (65.42)	p<0.0001
Familial history	Positive	86 (24.57)	χ^2 =89.52
	Negative	264 (75.42)	p<0.0001
Habits	Smoking	7 (2)	χ^2 =221.12
	Alcohol	5 (1.42)	p<0.0001
	Gutka/tobacco	112 (32)	
	All	20 (5.71)	
	None	94 (26.85)	

Table 5: Shows the anthropometric profile of the adults with type 2 diabetes mellitus.

Parameters		No. of adults [n = 350, (%)]
Hypertension	Normal (90 - 119/60 - 79)	130 (37.14)
	Pre-hypertension (120 - 139/80 - 89)	104 (29.71)
	Stage 1 (140 - 159/90 - 99)	76 (21.71)
	Stage 2 (>160/>100)	40 (11.42)
Blood glucose levels / lipid profile	FBG	251 (71.17)
	Cholesterol	122 (34.85)
	Triglycerides	136 (38.85)
Reasons for stress	Professional/occupational	122 (34.85)
	Family	67 (19.14)
	Any other	161 (46)
BMI	Under weight	15 (4.28)
	Normal weight	147 (42)
	Overweight	149 (42.57)
	Overweight Class I	39 (11.14)

* FBG - fasting blood glucose,# - BMI - Basal Metabolic rate.

Table 6: Shows the patients with diabetes diagnosed with tuberculosis.

Total no. of diabetes patients diagnosed with tuberculosis n =8 (2.2%)			Statistical analysis, χ^2, p value
Gender	Male	6 (1.71)	χ^2 =89.52, p<0.0001
	Female	2 (0.57)	
Mean age of patients		51.92±11.76	
Type of TB	Pulmonary	7 (2)	χ^2 =3.12, p=0.07
	Extra-pulmonary	1 (0.28)	
Category of treatment	CAT-I	8 (2.28)	χ^2 =6.12, p=0.01
	CAT-II	-	
Bacillary index (sputum positivity)	1+	5 (1.42)	χ^2 =7.00, p=0.07
	2+	1 (0.28)	
	3+	-	
	- ve	2 (0.57)	
Habits	Smoking	2 (0.57)	χ^2 =0.25, p=0.88
	All types	3 (0.85)	
	Nothing	3 (0.85)	
Life style	Active	4 (1.14)	χ^2 =0.0, p=1.0
	Sedentary	4 (1.14)	

Screening diabetes mellitus patients for tuberculosis

Table 4 and 5 depict the socio-demographic and anthropometric profile of patients with diabetes, respectively. Out of 350 patients, 75% were males, 28% each were in the age groups, 41-50 and 51-60 years, majority were well educated, 35% were having regular job, 65% were sedentary, 32% were addicted to tobacco whereas less than 2% either smoked or drank alcohol. 24% were having a positive family history, i.e., one of the members in their family; either parent or sibling was having diabetes. These socio-demographic factors appeared to be significant factors. RBG levels were high among 71%, cholesterol and triglycerides were raised among 34% of the diabetes patients. 29% were having pre-hypertension, 34% were having stress and 42% were overweight. Out of 350 patients with diabetes, 8 (2.2%) were having TB, 7 were new smear-positive PTB and 1 new extra-pulmonary TB (Table 6). Out of 350 patients with diabetes, 8 (2.2%) were having TB. Of these, 7 were new smear-positive PTB and 1 new extra-pulmonary TB. Mean age of the TB-T2DM patients were 51 ± 11 years, male gender, bacillary index of 1+ and Cat-I status appeared to be significant factors among patients having both the conditions (Table 6). The results showed that the incidence of TB among T2DM patients is less than that reported from other regions. They were referred to the TB clinic for further evaluation, treatment, care and management.

DISCUSSION

In this study, we determined the prevalence of diabetes among 350 TB patients registered in RNTCP in the Capital Hospital, Bhubaneswar. 17% of the TB patients were having diabetes. More males, married patients and those having less education were having Diabetes. The condition was more common with advancing age and sedentary life style. More TB patients were found to be addicted to either smoking, drinking alcohol and/or chewing tobacco / gutka. It was observed that 23% of the patients residing in housing colonies were having diabetes. Majority of patients with Diabetes were having pulmonary TB with 1+ sputum positivity and Cat-I type of treatment. Further, our results show that 13% were not aware that they were having Diabetes. Therefore, advancing age, illiteracy, having no specific job, inactive lifestyle, smoking/drinking, living in crowded areas, poor living conditions as well as unhygienic environment appeared to be the risk factors for diabetes among TB patients in Odisha.

Among 350 patients with T2DM attending the Diabetes Clinic, 8 (2.2%) were having active TB disease which is far less than that reported from other regions. Male gender, advancing age groups, fairly educated, having regular job, sedentary life style, addiction to tobacco, being overweight, having family history as well as high levels of RBG, cholesterol and triglycerides, hypertension, stress appeared to be the risk factors for TB among patients with diabetes. In our study, we observed that screening TB patients yielded more number of DM cases whereas screening patients with DM yielded less number of TB patients. Perhaps this could be the reason that in Odisha, RNTCP has implemented screening for DM among TB patients. However, more emphasis on additional manpower requirements and maintenance of medical records are required to improve case finding. A study by Vishwanathan et al showed that prevalence rates of DM and pre-diabetes were 25.3% and 24.5%, respectively, among TB patients registered under RNTCP in south India.[17] In two studies from Tanzania and Indonesia, 73% and 61% of diabetics, respectively, were newly diagnosed concurrent with active TB.[18,19] Similar studies have been carried out in China and Uganda.[20,21] The Diabetes has increased the burden of TB, especially in populations where the prevalence of TB infection is high among young adults.[22] In Odisha, the prevalence rate of DM is considered to be around 10 and rising fast and that of TB (i.e., 418 per 1,00,000 population) is below the national average (i.e., 445 per 1, 00,000 population).[23,24] DM prevalence rates ranging from 1.9% to 35% have been reported by screening for DM among TB patients across different regions of India.[25-27] The higher values were reported from regions with higher prevalence of DM. Many of the patients were newly diagnosed as a result of expansion of medical care related anti tubercular treatment.[28-30] The feasibility of screening DM at field level as well as the technologies used for assessment of blood glucose and co- management of TB-DM cases is a matter of concern.[31] Some studies suggest that high quality implementation research is required to find the value and methods of screening for DM in TB patients and vice versa and to set up standardised monitoring and evaluation systems.[32,33] Jeon et al have systematically reviewed studies that had screened for active TB or preventive therapy among people with DM, and those that screened for DM among patients with TB. Screening for TB in persons with DM demonstrated that TB prevalence is high, ranging from 1.7% in Sweden to 36% in Korea, and increasing with rising TB prevalence in the underlying population as well as with DM severity. Screening patients with TB for DM also resulted in high prevalence of DM ranging from 1.9% to 35%.[34] Few authors have carried out bi-directional studies.[35-38] Together these studies emphasize that the joint management of TB and DM should be carried out which, in turn, will improve clinical outcomes.

The strengths of this study are that we implemented bi-directional screening within the routine health system with no special budget allocated to support these activities. The early identification of patients with co-morbidity, especially among the newly diagnosed cases, is crucial in helping us to link these patients to appropriate DM care, which could lead to improved TB treatment outcomes.

Screening for TB using a symptoms based approach is cost-effective. In patients with active TB disease, the presence of history of diabetes needs to be confirmed at registration. Diabetes management during TB treatment needs to be monitored individually through estimation of blood glucose levels, supervision of diabetic medications, checking for complications / co-morbidities at regular intervals.

Limitations are we could screen small number of patients and analyzed the data over a short period of time. Some patients did not turn up for repeat testing; therefore, they were followed up by DOTS providers. About 7% of TB patients did not agree for a fasting blood test and 15% of DM patients did not opt for a TB screen. However, the loss to follow up was less, the primary reason being the close proximity of the TB and DM clinics in this hospital.

Another 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 hyperglycemia. This requires periodic blood glucose testing over the course of TB treatment, which was not done in this study. Further research is needed to ascertain this and the optimum timing of DM screening among TB patients. More research is warranted to investigate how the increasing incidence of DM impacts TB control efforts in Odisha.

CONCLUSION

Bi-directional screening of TB patients for DM and DM patients for active TB leads to earlier detection of DM as well as TB, better TB-specific treatment, favourable

outcome for TB as well as DM and prevention of DM complications. It is important in routine health care settings for monitoring disease progression and risk analysis which, in turn, would generate baseline data for planning further research studies and intervention strategies for prevention of several complications. The status of co-morbid conditions would guide the clinicians in deciding the appropriate treatment regimens and comprehensive management of at-risk individuals. An early treatment, if initiated, would help in further deterioration of the both conditions.

We, therefore, feel that bi-directional screening of TB and diabetes patients, irrespective of their complaints and symptoms, would go a long way in early detection of the both conditions.

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