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Active Tuberculosis Case Finding among Diabetic Patients: Bangladesh Program Experience

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Abstract

Background: Bangladesh is a highly populous country with high prevalence of TB and diabetes. Diabetes is associated with increased risk of TB, contributes to progression of latent TB in to active disease and increases the risk of latent TB infection. Limited access to TB and diabetes services is a barrier to increasing detection and management of TB among diabetics.

Methods: This is a retrospective review and analysis of the results of a pilot intervention designed to demonstrate effective and sustainable solutions for increasing detection of TB among diabetes patients. The results of the intervention were measured in terms screening of DM patients, TB case detection among diabetes patients and treatment outcomes. Data were collected from the Diabetic Association of Bangladesh which implemented the project with financial support of United States Agency for International Development (USAID).

Results: During the intervention period 510,953 diabetic patients were verbally screened for TB symptoms. A total of 1513 drug-sensitive TB cases and 16 rifampicin resistant TB (RR-TB) cases were diagnosed from among the diabetes patients screened through the intervention. Analysis of data shows that 70% of the diagnosed TB cases were among those living with diabetes for up to six months. Treatment outcome results of 1370 new patients are analyzed; 86% achieved favorable outcome which is lower than the national outcome. Treatment success rates largely varied by ages: highest success rate (91%) was found in 21-30 years age group and lowest (76%) in 61-70 years age group.

Conclusions: The intervention demonstrated that active case finding at facilities integrated with diabetes services is an effective approach to increasing detection of TB among diabetes patients. Scaling up of this model through upazila (sub-district) level health facilities is likely to significantly increase access to TB services for DM patients.

Keywords: TB; Diabetes; GeneXpert MTB/RIF; Active case finding

Introduction

The association between tuberculosis and diabetes, well established through studies, is a major challenge for global Tuberculosis (TB) control. The link between diabetes and TB has, most recently, been outlined in the WHO and the International Union against Tuberculosis and Lung Disease "Collaborative framework for care and control of tuberculosis and diabetes". Study findings indicate that the risk of TB is two to three times higher among people with diabetes than general population [1,2]. However, initiative for management of this dual burden of disease has been lacking in low and middle-income countries (LMICs) where TB is epidemic, and DM is perceived as being a minor problem. This perception is changing with the evidence of high prevalence of diabetes in many LMICs and the slower decline in global TB incidence [3]. Studies have shown that diabetes patients have impaired cell-mediated immunity, micronutrient deficiency, pulmonary microangiopathy and renal insufficiency, all of which predispose a patient to pulmonary tuberculosis [4]. Studies also indicate that patients with diabetes-TB have a higher bacillary load in sputum and take almost double the time for sputum conversion than non-DM patients [5]. In addition, more cavitary lesions are found in TB-DM patients [6,7] and thus they may be more infectious for the transmission of disease to other community members. They also present an altered immune response which likely predisposes them to increased susceptibility to infection with multidrug-resistant (MDR) strains of TB [8].

Bangladesh is one of the TB endemic high burden countries with incidence 221/100,000 and 40/100,000 death rate [9]. Notified TB cases is only 62% of the estimated incidence in 2016. Diabetes is also a daunting challenge with overall age-adjusted prevalence of diabetes and prediabetes at 9.7% and 22.4%, respectively [10]. Among urban residents, the age-adjusted prevalence of diabetes was 15.2% compared with 8.3% among rural residents. In total, 56.0% of diabetics were not

aware that they had the condition and only 39.5% were receiving treatment regularly [11]. There is no precise estimate of Type 1 and Type 2 diabetes for Bangladesh since most prevalence studies, conducted in adults, do not report the data separately. Prevalence of Type 1 diabetes is more common among children 0-14 years as in other countries. Using global incidence rate 3/100,000 among 0-14 years [12], approximately 1,700 children develop Type 1 diabetes every year in Bangladesh.

Prevalence of pulmonary TB among diabetes patients is estimated at 213 per 100,000 [13] which is almost double than that among the general population. The collaborative framework for care and control of TB and diabetes published by the World Health Organization (WHO) and the Union in 2011 outlines strategies to address these co-morbidities [14]. However, Bangladesh health systems rely on vertical service delivery programs for these two diseases at the expense of missed opportunities for effective bi-directional detection and management. Diabetes care in Bangladesh is provided primarily by the Diabetes Association of Bangladesh (DAB) at specialist clinics, tertiary-level specialist hospitals and district level outreach facilities. No routine TB services other than passive screening at the main DAB hospital in Dhaka were offered to diabetic patients. In 2013, USAID funded TB CARE II project with support of the National TB Control Program (NTP) first ever initiated a three-year intervention in partnership with DAB to offer active TB screening for DM patients at its facilities. This descriptive study is an attempt to present the results and lessons learned from this initiative to improve future programming and implementation.

Methodology

This is a retrospective review and analysis of the results from the integrated delivery of TB services for the diabetes patients in Bangladesh. We collected data for this study mainly from the DAB information system that was set up for performance monitoring of the TB-DM initiative supported by the TB CARE II project. Primary data from the DAB system for the whole intervention period from May 2013 to June 2015 were downloaded into an Excel spreadsheet. Quantitative analyses were performed to calculate aggregate number of DM patients screened, detection of TB among DM patients, duration of DM among patients diagnosed with TB, and treatment initiation by age and sex distribution. Additional data pertaining to training of service providers and detection of TB cases by GeneXpert MTB/RIF were retrieved from the TB CARE II project monitoring records and reports. Financial data was collected from TB CARE II project to estimate variable cost of additional TB case detection among diabetes patients. Treatment outcome data were analyzed for all patients to examine the proportions of patients who were cured or completed treatment, lost to follow-up, died, or had treatment failure.

Data quality and completeness were strictly maintained by regular monitoring and supervision visits by the project field staff. Periodic data quality audit was conducted by the TB CARE II project staff to verify accuracy of the performance data reported by DAB. No major data collection and management issues were observed except for delays updating treatment outcomes. All data collection and analysis were conducted according to international principles of maintaining privacy and confidentiality of personal information.

Intervention Design

The project was a pilot initiative to demonstrate effective and sustainable solutions for increasing detection of TB among diabetes patients. The intervention framework, as shown below, centered around capacity building of DAB staff for active case finding of TB among DM patients and referral linkages with DOTS centers for treatment and follow up services. Integration of TB with the existing DM services was an essential element of the design to increase access to TB services for the diabetic patients, reduce cost of services and advance financial sustainability of the initiative.

The WHO TB-DM collaborative framework recommends systematic TB screening of DM patients in countries with prevalence exceeding 100/100,000 population. Active screening for TB among people with DM was the core focus of the intervention as it could accelerate case detection leading to earlier therapy and prevention of transmission [15]. The TB prevalence being much higher in Bangladesh, the intervention design prioritized actions that were known to increase early access to screening for TB symptoms and signs, followed by diagnosis and prompt treatment which are critical for improving chances of survival, quality of life and reducing TB transmission in the service center as well as in the community. Implementation of Finding TB cases Actively, Separating safely, and Treating effectively (FAST) [16,17] was the intervention approach for active screening and transmission control at the entry level of facilities. Any diabetic patients with TB symptoms, specifically cough ≥ two weeks, were isolated immediately after the screening for diagnosis and management. The screening was conducted for both outdoor and in-ward patients. Light Emitting Diode (LED) microscopy and a GeneXpert MTB/RIF were installed at the main DAB hospital known as BIRDEM for rapid diagnosis of TB. Diagnosed TB cases after treatment initiation were linked with respective DOTS centers for treatment continuation and follow-up.

Capacity building

Major emphasis was given to developing DAB capacity for sustainable implementation of an integrated screening and management of TB-DM co-morbidity. Following the National Guidelines and Operational Manual for TB Control, the project assisted with the development of a TB-DM operational management guideline and training manual encompassing active screening, diagnosis, treatment, follow-up, referral, infection control, monitoring and reporting. Training capacity was institutionalized within DAB by training its staff as master trainers who trained 524 doctors, 491 nurses and 455 other health workers from the BIRDEM hospital and affiliated district facilities. With NTP support the project also facilitated installation of a GeneXpert MTB/RIF and a LED microscope as well as training of laboratory staff to enhance point-of-care screening capability at the BIRDEM hospital. The project also supported the design and implementation of a performance monitoring system including an Excel database for tracking, analyzing and reporting intervention results.

Geographic focus

The intervention was rolled out through Bangladesh Institute for Research and Rehabilitation for Diabetes, Endocrine and Metabolic Disorders (BIRDEM), which is the largest diabetes hospital in Bangladesh, as well as the district level DAB affiliated facilities that

provide mainly diabetes services. DM patients served by these facilities were the target beneficiaries of the intervention.

Results

For this review, we assessed the yield of screening for TB disease among people with DM as an outcome measure of this intervention. Following the national TB guidelines, entry level screening was done primarily based on cough for ≥ two weeks among the diabetic patients. During the intervention period, 510,953 diabetic patients who visited the outpatient department or admitted in to the hospital were verbally screened for TB symptoms. The TB presumptive cases were referred for sputum smear examination followed by chest X-Ray conducted for smear negative cases. GeneXpert MTB/RIF assay test was done primarily for all presumptive TB cases identified among the in-ward patients in BARDEM hospital. In addition, retreatment cases and cases with previous history of TB among outdoor patients were also referred for GeneXpert test following the national guideline. Table 1 presents the screening results and detection of TB cases among DM patients.

Indicators	Total	Sex	
		Male	Female
DM patients screened for TB	510,953	324,455	186,498
DM patients identified as TB presumptive	15,633	9,849	5,784
Patients diagnosed with Pulmonary Positive TB	795	569	226
Patients diagnosed with Pulmonary Negative TB	380	249	131
Patients diagnosed with Extra-pulmonary TB	338	172	166
Patients diagnosed with Rifampicin Resistant (RR) TB	16	9	7

Table 1: Screening DM patients for TB at DAB facilities, May 2013 to June 2015.

A total of 1513 additional drug-sensitive TB cases including 990 males and 523 females were diagnosed from among the diabetes patients screened through the intervention. Use of GeneXpert as a point-of-care diagnostic tool at the BIRDEM hospital greatly enhanced early detection of cases. Out of 3480 patients tested by GeneXpert MTB/RIF following national criteria, 430 bacteriologically positive TB sensitive to rifampicin and 16 rifampicin resistant cases were diagnosed. All the diagnosed patients were put on appropriate treatment regimen.

We have also collected disaggregated data to monitor any differences in TB disease distribution by age and sex of the diabetes patients (Table 2).

Age group	Total	Sex	
		Male	Female
≤ 20 years	106 (7%)	37	69
20-30 years	248 (13%)	113	81
31-40 years	194 (16%)	153	95
41-50 years	386 (26%)	240	146
51-60 years	354 (23%)	363	91
61- 70 years	170 (11%)	134	35
>70 years	56 (4%)	50	6
Total	1513 (100%)	990	523

Table 2: Age and sex distribution among diagnosed drug sensitive TB cases.

Although all the diabetic patients visiting the DM clinics were screened, very few TB cases were diagnosed from the patients living with diabetes for longer time. Analysis of data found that 70% of the diagnosed TB cases were among those living with diabetes for up to six months (Table 3).

Duration of DM	Number and Percent

≤ 3 months	691 (46%)
4-6 months	362 (24%)
7-9 months	107 (7%)
10-12 months	136 (9%)
>12 months	217 (14%)

Table 3: Duration of DM and number of TB diagnosed.

Among diagnosed patients 1370 were new and 143 were retreatment cases. All those patients were treated with daily DOTs at the DOTs center/TB clinics. Table 4 presents the outcome result of the 1370 newly diagnosed cases.

Outcome parameters	Total		Male		Female	
	Number	Percent	Number	Percent	Number	Percent
Total registered new patients	1370	100	903	100	467	100
Cured	523	38	385	43	138	30
Treatment completed	652	48	379	42	273	58
Died	95	6	69	8	26	6
Loss to follow up	74	5	53	6	21	4
Failure	26	2	17	2	9	2

Table 4: Outcome results newly diagnosed patients (all forms).

Discussion

A total 510,953 diabetic patients were screened for TB with focus on cough ≥2 weeks and other symptoms during the intervention period. Those with positive symptoms were referred to TB services for investigation, primarily using sputum smear microscopy. X-Rays and GeneXpert MTB/RIF tests were done specifically for smear negative and other cases as recommended by physicians after clinical examinations. Combination of these screening and diagnostics resulted in identification of large number of presumptive cases and detection of TB. Around 3% of diabetic patients were identified as TB presumptive cases of whom 10% were diagnosed with TB. Of the total 1513 drug-resistant TB cases diagnosed, 795 (53%) cases were bacteriologically positive, 380 (25%) cases were bacteriologically negative, and 338 (22%) were extra pulmonary TB cases. In addition, 16 rifampicin resistant TB cases were diagnosed with GeneXpert out of screening 3,480 drug-resistant presumptive cases. All the detected cases were initiated to treatment and notified to the national TB control program.

Detection of all forms of TB cases among DM patients as demonstrated through this intervention (296/100,000) is much higher than both the national incidence rate (221/100,000) [18] and prevalence rate (260/100,000) [19] of all form of TB among general population. Case detection rates of all forms of drug-sensitive TB for male and female is 305 and 280 per 100,000 diabetes patients reached through this intervention. Detection of bacteriologically positive (smear positive) cases was 155/100,000 which is much higher than the estimated national prevalence of 113/100,000 [20]. While this level of achievement is encouraging for a new initiative, the case detection rates are much lower than the estimated prevalence of TB among diabetes patients. Factors including quality of verbal symptom screening, limited access to X-Ray and GeneXpert as well as inadequate monitoring specifically at the district level diabetes facilities account for lower detection of TB cases than expected to a large extent. Nevertheless, the intervention amply justifies the effectiveness of the active case finding approach targeted to diabetic patients and other high-risk populations for increasing overall case detection and specifically bacteriologically positive infectious cases, which constituted 53% of all diagnosed cases. The intervention could also minimize the risk of TB transmission from one patient to another and to health care professionals which is high in health facilities especially countries with high disease burden [21,22].

Entry level verbal TB screening followed by smear microscopy and X-Ray for those found smear negative was the primary means for TB diagnosis. GeneXpert test was done mainly for in-ward patients, retreatment TB cases and others as recommended by the physicians. Symptom-based TB screening questions were built into the existing DM screening tool to ensure that no DM patients were excluded from the screening. The pediatric patients especially who couldn't produce sputum were referred to the pediatrician and diagnosed following the National Child TB Guidelines. Those who could produce sputum, the samples were checked by sputum smear microscopy and/or by GeneXpert. The integrated approach is shown to be cost effective although it was a challenge for the doctors to spend adequate time to ensure quality of screening given the overall patient load that they had to manage. The additional per TB case detection cost was only $97 excluding initial investments for training, diagnostic tools and development of screening tools, and materials for patient orientation.

The increased incidence of DM among TB patients is well known. It is not clear why DM patients, particularly those with poorly controlled disease, are at increased risk of TB, although changes have been found in both their innate and their adaptive immune responses. The exact mechanisms underlying this susceptibility to TB are still relatively undefined and need further investigation. However, as high yields are observed in these settings, program will need to decide on whether such screening is needed and, if so, what is the most cost-effective approach, and whether targeted screening is of better value than screening all patients.

The prevalence of bacteriologically confirmed TB is significantly higher among men in Bangladesh while there is not much difference in prevalence rate of diabetes [23] or estimated number of male and female diabetes patients (20-79 years) in Bangladesh [24]. This pattern as established through studies is not pronounced in the sex-specific data from the intervention presented here. That women screened for TB was only 37% of the total explains the difference in case detection by sex. Whether immuno-suppressive condition due to diabetes works as a levelling factor for men and women is for research to investigate. Only in the <20 years age group, 69 female patients were diagnosed with TB/DM. This is almost double that of the male patients (37). The reason for this difference is unknown.

It is hard to explain the significant variations observed in the number of TB cases among diabetes patients by duration of diabetes. Out of 1513 TB cases diagnosed, 691 (46%) were among patients diagnosed with DM within 3 months and only 217 (14%) among those living with DM for more than one year. The reason might be controlled and uncontrolled DM with those newly diagnosed DM patients' blood glucose was still not under control. Further investigation is needed to understand and explain these differences. Of the total diagnosed TB cases, 484 (31%) were Type 1 DM patients and 1029 (69%) were Type 2 DM. Since the intervention focus was only on detection of TB among DM patients, no Type 1 or Type 2 DM patient initially screened out for TB is included in the data presented here. Through this intervention, only 15 TB cased were found among the 0-14 age group of children screened for TB, much lower than expected. The intervention was in the tertiary level hospital and its affiliated clinics that offer specialized services for diabetic and pre-diabetic complications. This explains the reason for smaller number of children visiting these facilities and the lower number child TB cases detected.

All patients were treated with supervised daily short-course chemotherapy with first-line anti-tuberculosis drugs, namely Rifampicin (RMP), Isoniazid (INH), Pyrazinamide and Ethambutol. Sputum smear examinations were done at the end of 2nd, 5th and 6th month of treatment in new cases, and at the end of 2nd, 3rd, 5th and 8th month in retreatment cases. Treatment outcome was defined as 'cured', 'treatment completed', 'failure', 'loss to follow-up' and 'died', as per WHO guideline. Patients with 'cured' or 'treatment completed' outcome were considered as having a 'favorable outcome'.

Treatment outcome results of 1370 new patients are analyzed; 86% achieved favorable outcome which seems good but much lower than the national outcome. Among the patients with favorable outcome, only 45% patients have last sputum result at 6th month; other 55% did not appear for the test. Loss to follow-up and death rates are higher with 5% and 6% respectively. Since this is not a case-controlled trial, the reason of high rate of loss to follow-up and high death rate could not be identified. More structured study is needed to identify the reasons for high death rate. Little difference is observed in outcome result among male and female. Success rate is a bit higher in female (88%) whereas loss to follow-up (6%) and death rate (8%) is higher among male. Treatment success rates largely varied in different ages: highest success rate (91%) is found in 21-30 years age group and lowest (76%) is found in 61-70 years age group.

Diabetes is associated with increased risk of TB, is known to be a factor that contributes to progression of latent TB in to active disease and increases the risk of latent TB infection [25]. This raises public concern for Bangladesh where prevalence of both these diseases is very high. Increasing access to TB-DM services is critical for Bangladesh which aspires to achieve Universal Health Care (UHC) for its population by 2032 and Sustainable Development Goals (SDGs) for health. Achieving these goals require a major shift in the national service delivery strategy by integrating DM services with the communicable and curative care services at the upazila (sub-district) level which is the mainstay of the public health sector program. It is estimated that 60% of the people living with DM do not have access to treatment. A great opportunity lies in strengthening the upazila health systems with referral linkages to rapid diagnostic technologies such as GeneXpert to provide fast and easier access to DM services to this population and to prevent a co-epidemic of TB-DM in Bangladesh.

Conclusion

The intervention was piloted in Bangladesh for the first time to demonstrate feasibility to improve access to TB services for diabetes patients who are more vulnerable to infectious diseases. The increased detection of TB among diabetes patients shows a dire need for Bangladesh to revamp its TB control strategies with focus on active case finding approaches targeted to high risk populations. The intervention also demonstrated that simple integrated approach with existing services and strengthening support systems is the way forward to ensure universal access to health care and to reduce the burden of non-communicable and communicable diseases. The importance of high-level political support within countries as well as international financial and technical support for innovative health interventions need no further emphasis.

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