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Research article

Risk Factors of Active Tuberculosis and Tuberculosis Outcomes in Patients with Diabetes Mellitus: A Retrospective Matched Case-Control Study

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Abstract

Diabetes mellitus (DM) increases the risk of mortality and morbidities related to active tuberculosis (TB). Both diseases are common interlinked, particularly in high TB prevalence countries. Identifying the specific characteristics of patients with DM who later develop tuberculosis disease is crucial in promptly screening and early diagnosis of active TB. We therefore aimed to assess the predictor of active TB and TB treatment outcome among DM participants in Thailand. We conducted a retrospective cohort of 764 diabetic patients from January 2015 to December 2019 at King Chulalongkorn Memorial Hospital. Patients were categorized into "TB" and "no TB" group. To determine factors associated with incident TB were analyzed using Cox proportional hazard regression was done with 95% CI and p value < 0.05 considered significant. Out of total 764 diabetic patients, there were 509 DM without TB, 255 DM with TB. Of 255 DM with TB. 57 participants had DM at time of TB diagnosis. Overall prevalence of HIV infection was 2% and median age was 62.8 (QR 53.6-72.5) years. Median year of follow-up was 3916.2 person-years follow-up, the TB incident rate among diabetic patients was 45.96 (95%CI 39.72-53.19) per 100 person-years follow-up. The median HbA1c at the TB diagnosis was 8 (IQR 6.6-10.3). In multivariate analysis BMI<18.5 (aHR 3.78; 95%CI 2.47-5.78; p<0.001), smoking (aHR 1.95; 95%CI 1.23-3.10; p=0.004), HIV infection (aHR 3.31; 95%CI 1.59-6.86; p=0.001) were associated with active TB. Additionally, type of DM treatment was also related to active TB; insulin injection (aHR 1.60; 95%CI 1.02-2.51; p=0.04), combination treatment (aHR 1.66; 95%CI 1.02-2.70; p=0.04) and diet control (aHR 2.50; 95%CI 1.24-5.04; p=0.01) when compared with oral hypoglycemic drugs. Among TB cases, TB cure or treatment completion was 71.8%; 6.7% had TB relapse and 13.7% had drug resistance. Mortality rate of TB cases was 12.9%. The incidence of TB among DM cases observed in this study was high and it was associated with low BMI <18.5, smoking and HIV infection, pointing to the need to pay attention to these factors when managing this co-morbidity.

Introduction

Tuberculosis (TB) is a common infectious disease in Thailand. Thailand is listed of one of the 14 countries with high tuberculosis burden in the world. It is estimated that the annual number of new cases is approximately 120,000 with 12,000 deaths, and 2,200 cases of multidrug-resistant tuberculosis per year were reported. The National Tuberculosis Prevalence Survey in 2012-2013 estimated that the incidence rate of TB in 2014 was as high as 171 per 100,000 population [1].

Thailand has a newly diagnosed TB rate of 1.3 times which

is higher than the global average, but only 59% of the estimated cases detected and reported. This reflects delayed or inaccessible treatment for some patients, causing the spread of this infection to the community. and decrease the morbidity rate. Consequently, Thailand needs a strategy to halt the TB sequelae such as a high emerging rate of new infection and MDR TB infection [1].

Tuberculosis (TB) is a contagious disease caused by Mycobacterium tuberculosis. Tuberculosis can infect any organ of the body, especially in the lungs (80%), where it can be easily transmitted. Extrapulmonary tuberculosis may be found in other organs such as pleura, lymph nodes, spine, peritoneum, etc. Only about 10% of latent tuberculosis have symptomatic TB [2]. The likelihood of developing the disease increases in patients with low immunity, such as HIV infection and diabetes. Screening for those patients is important to early diagnose tuberculosis, reduce the spread of infection and have better treatment results. There are many studies on the risk of HIV co-infected with tuberculosis. However, the data on patients with diabetes remain lacking.

Several high-quality cohort studies have shown that diabetes is at an increased risk of developing active tuberculosis compared to general population and that those with poor diabetic control may be vulnerable [1,3-6]. The cause of the elevated risk is unclear and has not been thoroughly investigated.

Methods

Study population

This retrospective matched case-control study was carried out in diabetic patients treated at outpatient department of King Chulalongkorn Memorial hospital from January 2015 to December 2019 and we excluded the incomplete data patient from this study

Selection of case and control

The case group consisted of tuberculosis in diabetics. The control group consisted of diabetes patients who do not have tuberculosis in the King Chulalongkorn Memorial hospital database from January 2015 to December 2019. Regarding the number of controls per case, a 2:1 ratio was adopted.

Statistical analysis

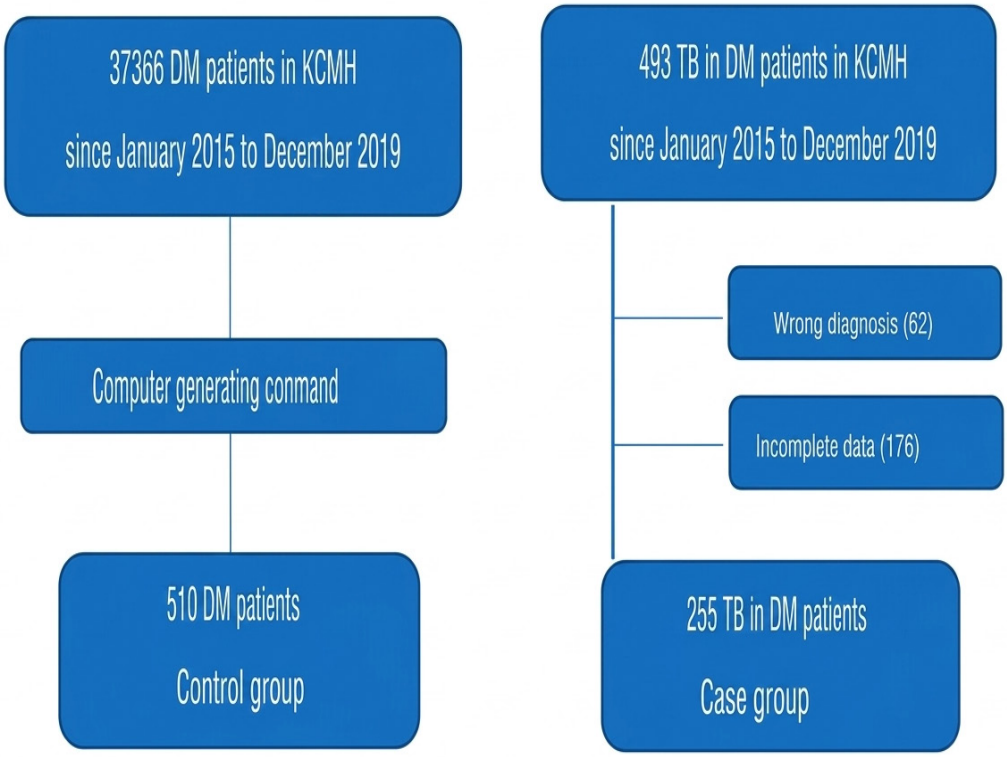
Continuous variables are described using medians and interquartile ranges (IQR), and categorical variables are presented as frequencies and percentages. Chi-square and Kruskal-Wallis were used to formally compare categorical and continuous variables between groups. Kaplan-Meier survival curves and the log-rank tests were used to estimate and compare incidence TB between groups. Cox proportional hazards model was used to determine factors associated with TB.

Ethical consideration

This study was approved by the Institutional Review Board of the Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand (IRB number 262/63); and data collection in the King Chulalongkorn Memorial hospital was authorized by the Information and technology department of the King Chulalongkorn Memorial hospital. The purpose of the research was the study about the risk factors of tuberculosis in patients with diabetes mellitus.

Results

From January 2015 to December 2019, 493 cases of TB in DM patients were recorded in KCMH database. After reviewing the data, 238 of which were excluded from this study, 62 patients were wrong diagnosis, 176 patients had incomplete data record. We included 255 cases of TB in DM patients for the case group. From 37366 cases of DM patients without TB recorded in KCMH database, we randomized by using computer generating command and included 510 cases into the control group. The prevalence of tuberculosis in diabetes patients in KCMH was



1.15% (from January 2015 to December 2019), and 57 (22.3%) first diagnosed diabetic patients at the TB diagnosis. We found that factors that were statistically different between DM with TB and DM without TB were age (>60-year-old), male gender, history of previous smoking, alcohol use, HIV infection, hypertension, dyslipidemia, chronic kidney disease, and treatment of DM (Table 1). But after the Cox proportional hazards model was used to determine the associated factors, we found only the low

Table 1: Characteristic of patient

Variables	Total (N=764)	DM no TB (n=509)	TB/DM (n=180)	TB before DM (n=75)	P-value
Age, median (IQR)	62.8 (53.6-72.5)	63.9 (55.7-73)	62.1 (52-75.8)	55.4 (49.4-64.9)	<0.001
Male, n (%)	407 (53.3)	231 (45.4)	116 (64.4)	60 (80)	<0.001
BMI, median (IQR)	24 (21.2-26.5)	25 (22.5-27.4)	21 (18.8-23.9)	22 (19.1-24.2)	0.001
•< 18.5 n (%)	63 (8.3)	10 (2)	39 (21.8)	14 (18.7)	<0.001
•18.5-22.9 n (%)	249 (32.6)	135 (26.5)	82 (45.8)	32 (42.7)	
•23-24.9 n (%)	151 (19.8)	107 (21)	30 (16.8)	14 (18.7)	
•≥ 25 n (%)	300 (39.3)	257 (50.5)	28 (15.6)	15 (20)	
Smoking, n (%)	152 (19.9)	55 (10.8)	61 (33.9)	36 (48)	<0.001
Alcohol use, n (%)	163 (21.3)	71 (14)	58 (32.2)	34 (45.3)	<0.001
Underlying, n (%)					
• CVA/TIA	73 (9.6)	55 (10.8)	17 (9.4)	1 (1.3)	0.03
• HT	523 (68.5)	390 (76.6)	97 (53.9)	36 (48)	<0.001
• DLP	415 (54.3)	340 (66.8)	62 (34.4)	13 (17.3)	<0.001
• TVD	35 (4.6)	25 (4.9)	9 (5)	1 (1.3)	0.37
• HIV	18 (2.4)	4 (0.8)	11 (6.1)	3 (4)	<0.001
• HBV	19 (2.5)	9 (1.8)	8 (4.4)	2 (2.7)	0.14
• HCV	10 (1.3)	4 (0.8)	5 (2.8)	1 (1.3)	0.13
• CKD	114 (14.9)	65 (12.8)	41 (22.8)	8 (10.7)	0.003
Complication					
Yes, n (%)	231 (30.2)	157 (30.8)	60 (33.3)	14 (18.7)	0.06
• Nephropathy UACR	123 (53.3)	82 (52.2)	32 (53.3)	9 (64.29)	0.06
• Neuropathy	5 (2.2)	4 (2.6)	0 (0)	1 (7.1)	
• Retinopathy	52 (22.5)	40 (25.5)	11 (18.3)	1 (7.1)	
• Other (PAD)	6 (2.6)	1 (0.6)	4 (6.7)	1 (7.1)	
• ≥ 2 complications	45 (19.5)	30 (19.1)	13 (21.7)	2 (14.3)	
Treatment DM					<0.001
• Oral hypoglycemia	504 (66)	380 (74.7)	82 (50.6)	42 (82.4)	
• Insulin injection	110 (14.4)	59 (11.6)	48 (29.6)	3 (5.9)	
• Combination	75 (9.8)	47 (9.2)	23 (14.2)	5 (9.8)	
• Diet control	31 (4.1)	21 (4.1)	9 (5.6)	1 (2)	
Kidney information					
Stage					0.20
• 3	57 (50)	30 (46.2)	21 (51.2)	6 (75)	
• 4	16 (14)	13 (20)	3 (7.3)	0 (0)	
• 5	41 (36)	22 (33.9)	17 (41.5)	2 (25)	
Treatment CKD					0.11
• Dialysis	25 (21.9)	12 (18.5)	11 (26.8)	2 (25)	
• Kidney transplantation	8 (7)	2 (3.1)	6 (14.6)	0 (0)	
• Medication	81 (71.1)	51 (78.5)	24 (58.5)	6 (75)	
BUN, median (IQR)	27 (20-45)	28 (20-44)	30 (20-47)	22.5 (20-28)	0.65
Cr, median (IQR)	1.9 (1.4-3.7)	2 (1.5-4.2)	1.6 (1.3-2.8)	1.5 (1.4-4.3)	0.05
eGFR, median (IQR)	31 (13-47)	26 (11-43)	35 (14-50)	41 (19.5-50)	0.22

Chi-square and Kruskal-Wallis were used to formally compare categorical and continuous variables between groups.
*We observed non-significant in CD4 cell count between group (DM: median (IQR), 316.5 (251-551.5) vs TB+DM: 103 (16-435) vs TB before DM: 474 (16-932); P-value=0.47).

BMI (<18.5), smoking history and HIV infection were significant (Table 7). Kaplan-Meier found the significant difference of the cumulative TB incidence in diabetes patient between the low BMI and other BMI, smoking and non-smoking (Graph 1). We found the HbA1C at the TB diagnosis was 8 (Table 2).

Table 2: Information for TB infection

	Total N=255
HbA1C at diagnosis, median (IQR)	8 (6.6-10.3)
Types of TB, n (%)	
• Pulmonary	224 (87.8)
• Extra-pulmonary	31 (12.2)
Smear: Positive, n (%)	110 (43.1)
Culture TB, n (%)	
• Positive	186 (72.9)
• Drug-resistance	35 (13.7)
TB Treatment regimen, n (%)	
• 2IRZE+4IR	161 (63.1)
• Other	94 (36.9)
Relapse, n (%)	17 (6.7)
Duration before diagnosis of tuberculosis (years), median (IQR)	3 (0.7-5.9)

*HbA1C were new TB (n=180) changes from at diagnosis were assessed with Wilcoxon sign-rank tests. We observed significant decreases in HbA1C (median (IQR) change -0.6 (-2.8 to 0.2) ; P-value<0.001).

Pulmonary involvement was found in 224 cases (87.8%), and extrapulmonary involvement was found in 31 cases (12.2%), The incidences of culture-confirmed, pulmonary, extrapulmonary, relapsed tuberculosis, the treatment regimen and duration of DM before TB were summarized in table 2. We identified the treatment outcome in table 3, 183 (71.8%) were cured or treatment complete, 5 (2%) were failure of treatment and mortality rate was 12.9%. The incident rate per 1000 person-years follow up was 45.96 (95%CI 39.72-53.19) and total person-time was 3916.18. Drug resistance TB was observed in 37 cases (14.5%) including multidrug resistant TB in 6 cases (2.35%), isoniazid monoresistance in 22 cases (8.63%) and rifampicin monoresistance in 2 cases (0.78%).

Discussion

The association between diabetes mellitus and tuberculosis has been reported but the previous data are notably scarce, possibly because of the practical difficulty many patients over a prolonged period, and none of the available studies specifically examined diabetic control as reflected by HbA1c. Indeed, notwithstanding the various acute and chronic infections frequently observed among diabetic subjects, relatively little is known

Table 4: Incident of drug resistance TB

Drug	n (%)
Multidrug resistance	6 (2.35)
Isoniazid	22 (8.63)
Rifampicin	2 (0.78)
Total	37 (14.5)

Table 3: Treatment outcome by TB group

Treatment outcome	Total n (%)	Pulmonary, only n (%)	Extra-pulmonary n (%)	P-value
Cured or treatment complete	183 (71.8)	159 (71)	24 (77.4)	0.46
Treatment failed	5 (2)	5 (2.2)	0 (0)	0.40
Lost to follow up				
(Culture: Positive at 5th month)	11 (4.3)	10 (4.5)	1 (3.2)	0.75
Death	33 (12.9)	29 (13)	4 (12.9)	0.99
Transfer out	23 (9)	21 (9.4)	2 (6.5)	0.59

Table 5: Incident rate per 1000 person-years follow up

Total person-time	TB onset	Incident rate	95%CI	
3916.18	180	45.96	39.72	53.19

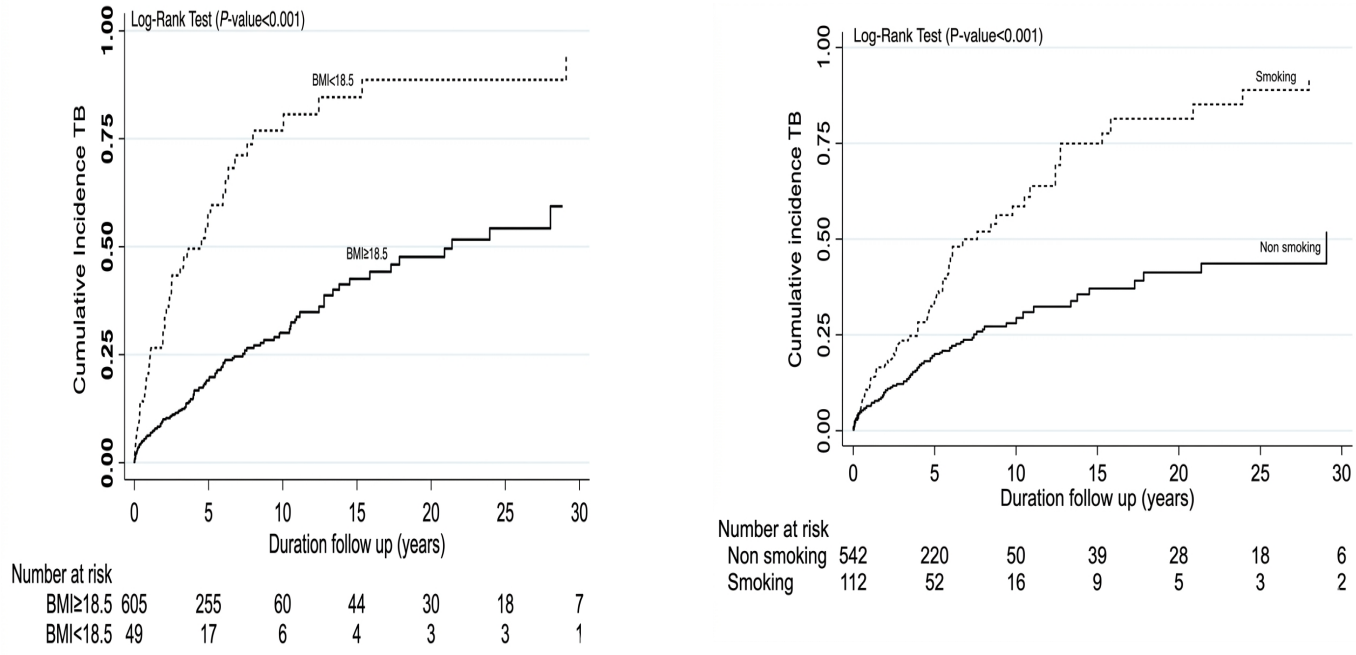
Table 6: Incident rate per 1000 person-years follow up by Treatment DM

Treatment DM	Total person-time	TB onset	Incident rate	95%CI	
Total	3827.46	162	42.33	36.29	49.37
• Oral hypoglycemia	2649.79	82	30.95	24.92	38.42
• Insulin injection	613.46	48	78.24	58.96	103.83
• Combination	454.47	23	50.61	33.63	76.16
• Diet control	109.74	9	82.01	42.67	157.62

Table 7: Risk factor associated with TB

	Univariate		Multivariate	
	HR (95%CI)	P-value	aHR (95%CI)	P-value
Age>60	1.41 (1.05-1.90)	0.02	1.26 (0.89-1.79)	0.20
Male	1.78 (1.31-2.42)	<0.001	1.08 (0.74-1.60)	0.68
BMI<18.5	3.73 (2.61-5.33)	<0.001	3.78 (2.47-5.78)	**<0.001**
Smoking	2.44 (1.79-3.33)	<0.001	1.95 (1.23-3.10)	**0.004**
Alcohol use	2.11 (1.54-2.89)	<0.001	1.10 (0.66-1.73)	0.80
Underlying				
• TVD	1.05 (0.54-2.06)	0.88		
• HIV	3.14 (1.68-5.87)	<0.001	3.31 (1.59-6.86)	**0.001**
• HBV	1.93 (0.95-3.92)	0.07	1.56 (0.69-3.50)	0.28
• HCV	2.47 (1.01-6.02)	0.047	1.75 (0.68-4.49)	0.25
• CKD	1.58 (1.12-2.25)	0.01	1.52 (0.97-2.37)	0.07
Complication of DM				
• No complication of DM	Ref 0.91 (0.65-1.28)	0.59		
• One complication of DM	0.72 (0.40-1.28)	0.27		
• Complication of DM≥2				
Treatment DM				
• Oral hypoglycemia	Ref		Ref	
• Insulin injection	2.58 (1.80-3.70)	<0.001	1.60 (1.02-2.51)	0.04
• Combination	1.66 (1.04-2.63)	0.03	1.66 (1.02-2.70)	0.04
• Diet control	2.36 (1.18-4.71)	0.02	2.50 (1.24-5.04)	0.01

Graph 1: Kaplan-Meier Incidence TB



about the underlying mechanism(s) or the exact role of diabetic control on infection risks [7,8]. The current study provided the associated factor of the primary impact of diabetic patients on the development of tuberculosis.

In this retrospective study of the risk of tuberculosis among people with DM in KCMH, we found the prevalence of tuberculosis was 1.15%. Compared with the overall prevalence of pulmonary TB in diabetics was shown to be 5.3% [9] which was lower than the estimated prevalence of TB in total population. This finding is in line with the studies conducted in Tanzania (5.4%) [10] and India (6%) [11].

The incident rate per 1000 person-years follow up is 45.96 (95%CI 39.72-53.19) and total person-time is 3916.18 in this study. DM increases the risk of TB by three-fold. (Relative risk 3.11; 95% CI 2.27-4.26) [5,12]. In this study the prevalence is lower than other studies, maybe from the small sample size and

the incomplete medical record from the physician. We found 57 (22.3%) first diagnosed diabetic patients at the TB diagnosis, so we suggest for DM screening at TB diagnosis by fasting plasma glucose and hemoglobin A1C.

In this study, we found the average HbA1C of the TB with DM was 8%, it can reflect that the poor glycemic control is the one of associated factors. Because of the poor glycemic control can cause the worse immune status of the diabetes patient, so they are increased risk of tuberculosis. Diabetic mice exhibit a critical delay in adaptive immune priming attributable to defective sentinel function of resident alveolar macrophage [8,13,14]. Once underway, the T cell response in diabetic mice appears to be functionally intact but quantitatively excessive, possibly reflecting higher antigen load and/or defective counter-regulation [8]. Other studies identified that the DM and TB group showed significantly higher levels of HbA1c and postprandial blood sugar, which indicates worse glycemic control compared to diabetics without TB [1,3]. Diabetic control was shown to be the predominant determinant of increased tuberculosis risk. Of some interest is the underlying reason why subjects with well-controlled diabetes mellitus were not at increased risk of pulmonary tuberculosis [4,5].

Low BMI (<18.5) is a significant associated factor in the study. Abera, A. revealed that those DM patients who were underweight (BMI <18.5Kg/m2) had about ten times high odds TB infection with DM. Similar finding was found in a study conducted in Chiayi, Taiwan (15) [OR = 6.635, 95% CI: (2.096-21.007)], a study conducted in India (16) [AOR = 2.03, 95% CI: (1.32–3.12)] and in Tanzania [17] [OR = 2.08 955 CI: (1.06–4.06)]. BMI indicates malnutrition which is a factor for several infectious diseases. Underweight individuals have a weak immunity system which exposes them to infection [9,8]. But in other studies, showed that being overweight and obesity were risk factors for DM but were protective against TB disease [5,6]. However, weight loss due to poorly controlled DM and metabolic decomposition takes away this protection and becomes risk factor for TB [6].

HIV co-infection is a strongly associated factor in the study. Because of HIV infection people have acquired CMIR defect by immune alteration from the infection, so they can develop active tuberculosis easier than non-HIV patients. HIV status is another important factor strongly associated with TB [2,3].

Smoking history is a significant associated factor in univariate in Cox proportional hazards model in this study but not significant in multivariate method. A study in Taiwan with a cohort of diabetics showed that smoking increases twice the risk of becoming ill with TB. The possible mechanisms that increase a smoker susceptibility to develop TB include a decrease in the immune response due to the dysfunction of ciliary mechanics on the surface of the tracheobronchial mucosa, defects in the immunological response of macrophages, and the reduction of CD4 level [19].

Male gender, older age, alcohol use are tended to be associated factors with developing tuberculosis in diabetes patient but those are not significant. Lifestyle is the important thing that easily leads to infection. Many other studies found that TB-DM comorbidity was significantly more common in patients over 40 years [1]. Because of the worsening of the immune system. Regular drinking is one of the factors that negatively influences adherence to drug treatment, contributing to poor glycemic control and predisposing to complications. In addition, excessive alcohol users are immunologically compromised, which increases the risk of contracting TB as well as the reactivation of latent TB. Although alcohol provides calories, without nutritional support it predisposes to gastric problems, which in turn impair the individual's nutritional status. Alcohol suppresses monocytes' ability to produce cytokines, which directly inhibit bacterial growth and play a key role in cell communication, activation, proliferation and migration, as well as regulation of inflammation and healing mechanisms [19].

Regarding TB treatment outcomes, we identified 183 (71.8%) were cured or complete treatment, 5 (2%) were failure of treatment and mortality rate was 12.9%. The mortality rate was too high as compared with other studies that the risk of death from TB or any other causes was nearly 2-fold (RR 1.89; 95% CI 1.52-2.36) [5]. Because of the delayed diagnosis from many causes such as the symptoms aren't specific or no symptoms, the change in immune system, and improper screening to find out the tuberculosis which causes severe lung destruction.

Multidrug resistant TB was detected in 6 cases (2.35%), Isoniazid resistance TB was 22 cases (8.63%), Rifampicin resistance TB was 2 cases (0.78%). But in other studies, the prevalence of drug-resistant or MDR TB among recurrent TB cases was not significantly higher in TB-DM patients. (OR 1.24, 95% CI 0.72-2.16) [13].

Conclusion

The incidence of TB among DM cases observed in this study was high and it was associated with low BMI <18.5, smoking and HIV infection, pointing to the need to pay attention to these factors when managing these co-morbidities. Screening TB disease in DM may be another target to achieve better TB control by earlier TB diagnosis and treatment, resulting in reducing TB transmission and better treatment outcomes in TB-DM patients.

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