

## A CASE CONTROL STUDY ON CLINICAL CHARACTERISTICS AND TREATMENT OUTCOMES IN TUBERCULOSIS PATIENTS WITH DIABETES IN PALAKKAD DISTRICT

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### ABSTRACT

The association between diabetes and tuberculosis (TB) is an area of growing interest due to the persistent high prevalence of both diseases internationally. Diabetes is a known risk factor for the development of active TB, so this study was planned to found out the effect of diabetes on TB among the patients of Palakkad district in Kerala state. The aim of the study was to evaluate the clinical manifestations and treatment outcomes in tuberculosis patients with diabetes. This prospective case control study was conducted in district tuberculosis centre Palakkad. About 130 cases were collected from tuberculosis unit, District hospital Palakkad. It has been observed that majority of the diabetic patients were pulmonary TB cases (89.36%). In diabetic TB cases the percentage of failure, death, multidrug resistant TB (MDR-TB) and extensively drug resistant TB (XDR-TB) are 12.77%, 2.13, 14.89, 2.13 respectively which is higher than the results of TB patients without diabetes. The sputum smear positivity after intensive phase of TB treatment was also high among diabetic TB patients (56.41%).

**Keywords:** Tuberculosis, Diabetes, Pulmonary TB, Extra pulmonary TB.

### INTRODUCTION

Globally, there are an estimated 8.8 million new tuberculosis (TB) cases each year, and approximately 340 million people are living with diabetes. Diabetes is a known risk factor for the development of active TB, and an estimated 15% of patients with TB in countries with a high TB burden have diabetes. The association between diabetes and TB is an area of growing interest due to the persistent high prevalence of both diseases internationally<sup>1</sup>. Diabetes is currently an important chronic disease mainly in developed countries. In developing countries the prevalence of diabetes is also soaring. Many studies have shown that the prevalence of TB among diabetics, especially in those with poor glycemic control, is higher than innondiabetic

population<sup>2</sup>. The countries like China and India with large populations and low to middle incomes have the highest number of TB patients and are facing a rapid increase in the number of diabetic patients as well. Since TB is an air-borne infectious disease that transmits from person to person, each index case of TB can infect an average 10 persons in a year<sup>3</sup>. Over the past few years, some studies have shown that the treatment failure rate is higher in TB patients complicated with diabetes. Moreover, there is a significant association between diabetes and multidrug resistant TB (MDR-TB)<sup>4</sup>.

Besides the disease burden, TB also causes an enormous socio-economic burden. Each year, more than 300,000 children leave school permanently because of their parents TB, and

more than 100,000 women are rejected by their families on account of TB. TB costs India more than \$300 million annually in direct costs alone, of which more than \$100 million is incurred in the form of debt by parents and their families.<sup>5</sup> Both TB and diabetes are major public health problems and the link between the two diseases should be paid special concern<sup>6</sup>. Hence, the current study was planned to found out the effect of diabetes on TB among the patients of Palakkad district in Kerala state.

#### **MATERIALS AND METHODS**

This was a prospective case control study conducted at District Tuberculosis Centre Palakkad for evaluating the effect of diabetes in clinical characteristics and treatment outcomes in TB patients. The study protocol was approved by the institutional ethical committee (GCP/IEC/625/2014).

#### **Study population**

The study was conducted on 130 TB patients. Out of 130, 97 were male patients and 33 were female patients. The patients were selected on the basis of inclusion and exclusion criteria. Patients without diabetes are taken as the control group and patients with diabetes are taken as the test group.

#### **Inclusion criteria**

Patients above 18 years of age and Patients with TB both diabetic and non diabetic.

#### **Exclusion criteria**

HIV patients with TB and Patients unwilling to participate.

#### **Data Collection**

Using data collection forms (it included patient demography, site of infection, diabetic status, medication information and lab investigations).

#### **Duration of the study**

Seven months (January to July 2014).

#### **Statistical Analysis**

Done using Graph Pad InStat version 3.

#### **RESULTS AND DISCUSSION**

About 130 tuberculosis patients fulfilling the study criteria was taken, out of which 47 cases comes under test group and 83 cases comes under control group. The distribution of patients according to site of infection is shown in table 1. Out of 47 cases in the test group 42 cases were pulmonary TB patients and only 5 cases were extra pulmonary cases. Figure 1

shows the graphical representation of distribution of patients according to site of infection. The treatment outcome of patients is given in table 2, in diabetic TB cases the percentage of failure, death, MDR-TB and extensively drug resistant TB (XDR-TB) are 12.77%, 2.13, 14.89, 2.13 respectively which is higher than the results of control group patients. Table 3 and figure 3 gives the distribution of pulmonary TB patients based on sputum smear positivity at the end of intensive phase of TB treatment. About 56.41% of pulmonary TB cases in test group were sputum positive after intensive phase of treatment while only 26.53% of cases in control group. This result was found to be statistically significant ( $P < 0.05$ ).

In the study it has been observed that the prevalence of pulmonary TB is higher in diabetic patients and also the patients with extra pulmonary TB were found to be comparatively very less. The result was found to be statistically significant ( $P < 0.05$ ). This data is similar to the previous studies<sup>7,8</sup> and suggest that the prevalence of pulmonary TB is more in diabetic patients than the TB only patients. The treatment failure cases in diabetic TB patients were higher than that of the TB only patients. This result was also found to be statistically significant ( $P < 0.05$ ). Percentage of patients with MDR-TB and XDR-TB were high in diabetic patients than in TB only patients. The sputum smear status after intensive phase of TB treatment also shows that the majority of patients in diabetic group were sputum positive, while majority of cases in TB only group were sputum negative after intensive phase of TB treatment. This data is similar to the result of previous study<sup>9</sup> conducted. The treatment failure rate and the risk of MDR-TB and XDR-TB are found to be more in diabetic patients. So this indicates that the TB treatment is found to be suboptimal in diabetic patients. Normal TB treatment took around six months, but since the MDR-TB and XDR-TB rates are more in diabetic patients they are prone to more than one year of TB treatment.

#### **CONCLUSION**

Pulmonary TB is more predominant among diabetic patients, so the transmission of disease will be high. It has been found that the treatment failure cases are high among diabetic TB patients. So it has been proved that the effectiveness of anti tubercular drugs in diabetic patients is comparatively less. The prevalence of MDR-TB and XDR-TB is also high among diabetic patients. Sputum conversion is found to be delayed in

pulmonary TB cases with diabetes; this also shows that the TB treatment is found to be suboptimal in diabetic patients.

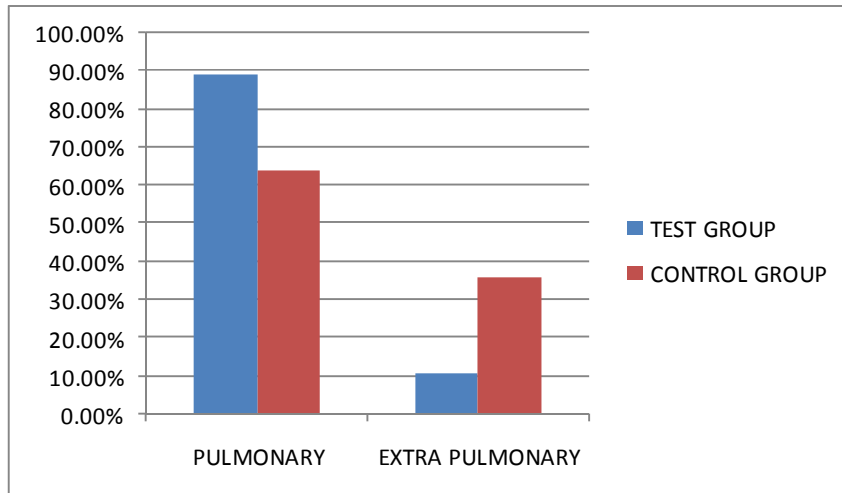
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**Table 1: Distribution of Patients According to Site of Infection**

Site of infection	Test group N = 47		Control group N = 83		p-value
	N	%	n	%	
Pulmonary	42	89.36	53	63.85	0.0018
Extra pulmonary	5	10.64	30	36.15	



**Fig. 1: Distribution of Patients According to Site of Infection**

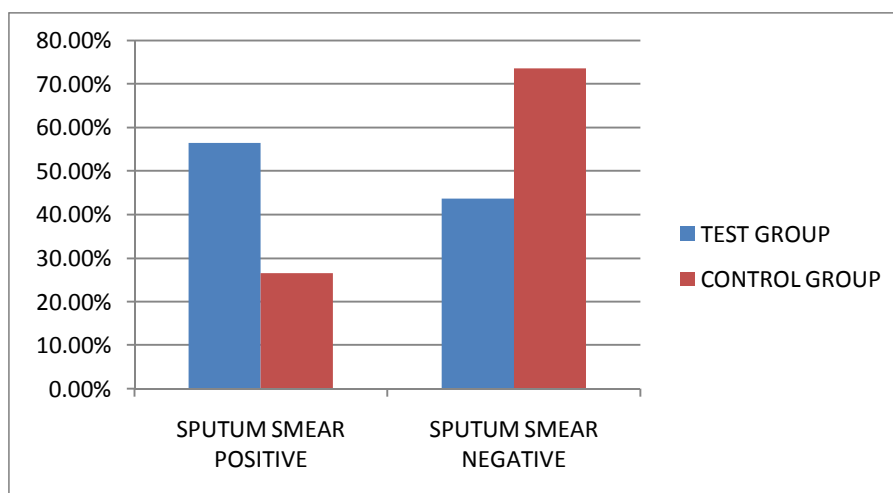
**Table 2: Distribution of patients according to treatment outcome**

Treatment outcome	Test group N = 47		Control group N = 83		p-value
	n	%	n	%	

Cured	18	38.29	40	48.19	0.4171
Failure	6	12.77	2	2.41	0.0222
Death	1	2.13	1	1.21	0.6836
MDR-TB	7	14.89	7	8.43	0.2809
XDR-TB	1	2.13	1	1.21	0.6836
Treatment defaulters	1	2.13	4	4.82	0.4522
<u>Patients under category 1 intensive phase treatment</u>					
With clinical improvement	5	10.64	17	20.48	0.1899
Without clinical improvement	8	17.02	11	13.25	0.5892

**Table 3: Distribution of pulmonary TB cases based on positive sputum smear at the end of intensive phase of TB treatment**

Sputum smear	Test group N = 39		Control group N = 49		p-value
	n	%	n	%	
Positive	22	56.41	13	26.53	0.0086
Negative	17	43.59	36	73.47	



**Fig. 2: Distribution of pulmonary TB cases based on positive sputum smear at the end of intensive phase of TB treatment**

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