"PREVALENCE OF DIABETES MELLITUS AMONG TUBERCULOSIS PATIENTS REGISTERED UNDER REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME"

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This is to certify that the dissertation entitled **"PREVALENCE OF DIABETES MELLITUS AMONG TUBERCULOSIS PATIENTS REGISTERED UNDER REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME"** is a bonafide and genuine research work done by **REG. NO.BD0111004.**

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LIST OF ABBREVIATIONS USED

AFB – Acid Fast bacilli

ALT – Alanine Transaminase

DM – Diabetes Mellitus

DMC – Designated Microscopic Centre

DOTS – Directly Observed Treatment Short Course

FBG – Fasting Blood Glucose

HbA1c – Glycosylated Hemoglobin

HIV – Human Immunodeficiency virus

HSP- Heat shock Protein

IFN ɣ - Intereferon ɣ

IGT – Impaired Glucose Tolerance

IL-1 – Interleukin 1

LCFAs – Long Chain Fatty Acids

MDR TB – Multi Drug Resistant Tuberculosis

NFHS – National Family Health Survey

NGO – Non Governmental Organisation

OGTT – Oral Glucose Tolerance Test

OR – Odds Ratio

PHC – Primary Health Centre

PMN – Poly Morpho nuclear neutrophils

RNTCP – Revised National Tuberculosis Control Programme

ROS – Reactive Oxygen Species

TB - Tuberculosis

Th 1 – T Helper Cell 1

TNFα – Tomour Necrosis Factor ∞

UHC – Urban Health Centre

WDF- World Diabetes Federation

WHO – World Health Organisation

ABSTRACT

Introduction

India has the highest burden of tuberculosis accounting for one fifth of the global incidence with an annual estimate of approximately 2 million cases. Global tuberculosis control is being undermined by the growing number of patients with diabetes mellitus. There are around 36 million diabetics in India which is estimated to increase to 80 million by 2030. Active detection of diabetes amongst tuberculosis patients may provide an opportunity to identify previously undiagnosed diabetes, to offer optimum diabetic care and improve the treatment outcomes of tuberculosis.

Objectives

To find the prevalence of diabetes mellitus among tuberculosis patients registered under Revised National Tuberculosis Control Programme and to compare the socio demographic and clinical profile of patients with tuberculosis and diabetes mellitus with that of tuberculosis alone.

Methodology

A cross sectional study was done for one complete year in three primary health centres - Handignoor, Vantamuri, Kinaye ; three urban health centres- Ram Nagar, Asok Nagar, Rukmini Nagar and in Revised National Tuberculosis Control Programme unit, Government District Hospital Belgaum. A total of 437 tuberculosis patients were enrolled in the study. Patients were first screened with fasting blood glucose and later diagnosis of diabetes mellitus was confirmed with oral glucose tolerance test.

Results

In the present study the prevalence of DM among TB patients was found to be 21.1% of which one third of the cases were newly diagnosed. On comparison of socio-demographic and clinical profile of patients of TB-DM with that of TB, the study observed significant difference between the two groups with respect to age group commonly affected (41-70 years vs 21-40 years), male: female ratio (3:1 vs 1.9:1), highly symptomatic at presentation (85% vs 56%), higher body mass index (17.4% vs 5.5%), greater waist circumference in males and females, pulmonary form of tuberculosis (90.2% vs 82.6%), high bacterial load of ++/+++ (57.6% vs 28.6%), relapse and failure cases (17.6% vs 8.4%) and HIV positivity (27.5% vs 12.8%).

Conclusion

The high prevalence of diabetes among tuberculosis patients may adversely affect the outcome of tuberculosis treatment. Hence screening of all tuberculosis patients for diabetes must be routinely done.

Key words

Diabetes mellitus, Tuberculosis, Revised National Tuberculosis Control Programme.

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INTRODUCTION

Tuberculosis (TB) is the second leading cause of death from an infectious disease next to Human Immuno-deficiency Virus (HIV) infection.[1] In 2011, there were an estimated 8.3 million incident cases and 1 million deaths due to tuberculosis.[1] Despite control strategies, tuberculosis remains a major public health problem in many countries. Along with effective control measures currently available, it is essential to identify and target the risk factors of developing active TB so as to tackle the heavy burden of the disease. Diabetes mellitus (DM) is a clinically and genetically heterogeneous group of disorders that have one common feature ie; abnormally high levels of glucose in the blood either due to insulin deficiency or insulin resistance. DM reduces immunity and has long term complications affecting all vital organs of the body. It was a well known risk factor for TB in the past, but this was largely forgotten during the second half of the 20th century because of widely available treatment for both diseases.[2,3] Now with the current global increase in DM cases, which currently stands at an estimated 285 million and is anticipated to reach 438 million by 2030, the association between TB and DM is re-emerging.[4] The World Health Organization (WHO) suspects that global TB control is being undermined by the growing number of patients with DM. Experts have raised concerns about the twin epidemics of DM and TB, especially in low- to middle-income countries like India and China.[5,6]

According to a recent meta-analysis, diabetics have three times the risk of contracting TB as compared to non-diabetics[7] and studies report the fraction of

TB cases attributable to diabetes to be between 15% and 25%.[8] The biological basis for the association between both diseases is that diabetes decrease the immune response, which in turn facilitates TB infection and progression to symptomatic disease. While the association between TB and DM seems not to be in doubt and has been talked of at various platforms, it has never occupied the attention it deserves. The available evidence from various previous studies have limitations like many of them were facility based, many were carried out in industrialized countries and none of the studies used oral glucose tolerance test (OGTT) to diagnose DM. Moreover additional issues which need further clarification in this dangerous liaison are 1) drug interactions 2) treatment outcomes 3) TB recurrence and development of multi drug resistant tuberculosis (MDR-TB).

India has the highest burden of TB accounting for one fifth of the global incidence with an annual estimate of approximately 2 million cases.[1] According to National Family Health Survey (NFHS) III data, there are around 36 million diabetics in India which is estimated to increase to 80 million by 2030.[9] Active detection of diabetes amongst TB patients may provide an opportunity to identify previously undiagnosed diabetes, to offer optimum diabetic care and improve the outcomes of TB treatment and prevent the relapse of TB.

At present Revised National Tuberculosis Control Programme (RNTCP) gives policy guidance to actively detect diabetes in tuberculosis patients but do not provide recommendations regarding the treatment protocol and follow up of patients with co existing TB and DM. There are few studies from this part of the country showing the prevalence of diabetes among TB patients. Due to this

paucity our study was a sincere attempt to find out the actual prevalence of DM among TB patients and thus provide evidence for screening of TB patients for DM.

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OBJECTIVES

The objectives of the present study were;

- To know the prevalence of diabetes mellitus among tuberculosis patients registered under revised national tuberculosis control programme

- To study and compare the clinical and socio- demographic profile of patients with co- existent diabetes and tuberculosis with patients of tuberculosis alone.

REVIEW OF LITERATURE

History of TB

Tuberculosis (TB) caused by Mycobacterium tuberculosis (*M. tuberculosis*), is one of the oldest disease known to mankind which might have killed more persons than any other microbial pathogen. The earliest evidence of tuberculosis infection in humans is obtained from Egyptian mummies dated between 3700-1000 BC. The Hindus called this disease *sosha* (cough) or *rajayakshma* (wasting). The Greeks named it *phthisis* (to waste), and in Roman times this condition was *tabes* (a near equivalent to phthisis). Once the English speaking world developed, the familiar term *consumption*- derived from Latin *consume*r (to consume or wear away) entered the literature. The many detailed accurate description of tuberculosis patients attest to the ancient physicians' trenchant powers of observation. They all recognized the disease's cardinal signs – cough, expectoration, hemoptysis, and wasting of the body. The first three signs placed the problem squarely in the respiratory system. The fourth led to speculation that the disease's impact eventually extends well beyond the lung. In the second book of the *De Morbis*, Hippocrates (460-400 BC) noted the general appearance of the consumptive – languorous, emaciated, and physically debilitated with red cheeks.

With the development of large cities, shifts in population, and the spread of commerce, pulmonary tuberculosis spread relatively quickly. It is clear from writings produced during the last several centuries of the first millennium BC that pulmonary tuberculosis had spread throughout the world. In the Indian literature,

the *Atharva-Veda* (400 BC) counsels: *The physician who values his reputation should not undertake to take care of a patient who has the three great symptoms: fever, cough, and bloody sputum. If, however the patient has a good appetite and digests well the food and the disease is in its infancy, a cure may be hoped for.*

Until the latter half of the nineteenth century two types of theories held sway regarding the cause of tuberculosis. One centered on contagion. The other included precipitating factors from nature (inheritance) or nurture (psychological stress) or both. *Phthisiologia*, the first systematic treatise on TB, written in England in 1689 by Richard Morton listed 11 causes of tuberculosis in order of importance. Most important was the inability to purge the body of a noxious substance, whether menstrual blood, pus or sweat. Next came mental imbalance caused by passions and pre occupations. Hereditary predisposition was seventh on Morton's list and infection was dropped to the ninth place. The eighteenth century saw tuberculosis reach epidemic proportions. In 1819 Rene Theophile Hyacinthe Laennec, the inventor of stethoscope, came up with his unifying theory of tubercle. He insisted that tubercle wherever it might occur represented this one disease- phthisis. All speculation and arguments regarding the etiology of tuberculosis came to an end by the discovery of tubercle bacillus by Robert Koch in 1882. The discovery of tubercle bacillus finally gave substance to the thought that the disease can now be controlled by paying attention to this germ which if neutralized or destroyed in the beginning of the disease would be the best possible remedy. But it still took another 60 years before Schatz, Bugie and Waksman came up with a reliable cure for the disease by discovering streptomycin.

History of DM

The history of diabetes dates back to 1550 BC with the first reference of the disease in an Egyptian papyrus which mentions a rare condition of “too great emptying of urine” and causes the patient to lose weight rapidly. Indian physicians around the same time identified the disease and classified it as *madhumeha* or *honey urine* noting that the urine would attract ants. The term "diabetes" or "to pass through" was first used by the Greek Appollonius of Memphis (230 BC). Type 1 and type 2 diabetes were identified as separate conditions for the first time by Indian physicians Sushruta and Charaka with type 1 associated with youth and type 2 with overweight. The first complete clinical description of diabetes was given by the Greek physician Aretaeus of Cappadocia (1st century CE), who also noted the excessive amount of urine which passed through the kidneys. Diabetes appears to have been a death sentence in the ancient era. Hippocrates makes no mention of it, which may indicate that he felt the disease was incurable. Aretaeus did attempt to treat it but could not give a good prognosis and commented that "life (with diabetes) is short, disgusting and painful." Avicenna (980–1037), the Persian physician, provided a detailed account on diabetes mellitus in *The Canon of Medicine*, describing the abnormal appetite and the collapse of sexual functions and documented the sweet taste of diabetic urine. He also described diabetic gangrene, and treated diabetes using a mixture of lupine, trigonella (fenugreek), and zedoary seed, which produces a considerable reduction in the excretion of sugar, a treatment which is still prescribed in modern times.

The term "mellitus" or "from honey" was added by Thomas Willis in 1674 in his book *Pharmaceutice rationalis* to separate the condition from diabetes insipidus which is also associated with frequent urination. In 1776, Matthew Dobson confirmed that the sweet taste comes from an excess of a kind of sugar in the urine and blood. The discovery of role for the pancreas in diabetes is generally ascribed to Joseph Von Mering and Oskar Minkowski, who in 1889 found that dogs whose pancreas was removed developed all the signs and symptoms of diabetes and died shortly afterwards. The islets of Langerhans, key cells in the pancreas, was discovered in 1869 by an anatomist named Paul Langerhans. In 1910, Sir Edward Albert Sharpey-Schafer suggested that people with diabetes were deficient in a single chemical that was normally produced by the pancreas—he proposed calling this substance *insulin*, from the Latin *insula*, meaning island, in reference to the insulin-producing islets of Langerhans in the pancreas. The endocrine role of the pancreas in metabolism, and indeed the existence of insulin, was further clarified in 1921,by Sir Frederick Grant Banting and Charles Herbert Best who demonstrated that induced diabetes in dogs can be reversed by giving them an extract from the pancreatic islets of Langerhans of healthy dogs. Banting and Best went on to purify the hormone insulin from bovine pancreas for which they received Nobel Prize in 1923. This led to the availability of an effective treatment—insulin injection—and the first patient was treated in 1922

Global burden of TB[1]

According to WHO Global Tuberculosis Report 2012; there were an estimated 8.7 million incident cases of TB globally in 2011; which is equivalent to 125 cases per one lakh population. Most of the estimated number of cases occurred in Asia (59%) and Africa (26%). India and China alone accounted for 26% and 12% of global cases, respectively. Of the 8.7 million incident cases in 2011, 1.0 million – 1.2 million (12–14%) were among people living with HIV. Incidence rates are declining in all of WHO's six regions. The rate of decline between 2010 and 2011 was 2.0% in the South-East Asia Region, The maximum rate of decline in incidence rates is seen in the European Region (8.5%) and miminum in the Eastern Mediterranean Region (0.5%). There were an estimated 12 million prevalent cases (range, 10 million–13 million) of TB in 2011 equivalent to 170 cases per 100 000 population. The prevalence rate has fallen by 36% globally since 1990. The number of TB deaths worldwide fell just below 1 million among HIV-negative people in 2011. This was equivalent to 14 deaths per 100 000 population. There were also an additional 0.43 million HIV-associated deaths (0.40 million–0.46 million) i.e. deaths from TB among people who were HIV-positive.

Burden of TB in India[10]

India is the country with the highest burden of TB in the world. There were an incident 2.3 million cases of TB during the year 2011 which corresponds to 185 cases per 1 lakh population. The overall prevalence of TB was 3.1 million which corresponds to 256 cases per 1 lakh population. The number of deaths due to TB

was 0.32 million (26 per 1 lakh population). HIV- TB co infection was seen in 0.11 million cases (5%). The prevalence of multi drug resistant TB (MDR-TB) was found to be 2.1 % among the new pulmonary TB patients whereas it was 15% among the retreatment pulmonary TB cases.

Global burden of DM[4]

Globally there were 366 million people affected with DM in the year 2011 which is projected to rise to 552 million by 2030. The global prevalence is 8.3% with low and middle income countries bearing 80% of the burden. The greatest number of diabetic people is in the age group 40-59 years. DM caused 4.6 million deaths worldwide in 2011.

Burden of DM in India[11]

In 2011, there were 61.3 million diabetics in India and this figure is estimated to reach 101.2 million by 2030. The prevalence among males is 11.1% whereas in females it is 10.8%.

Association between TB and DM

Since ancient times, physicians have been aware of the association between tuberculosis and diabetes mellitus: perhaps the earliest to note it was the great Indian physician Sushruta, in 600 A.D, while Avicenna (980-1027 A.D) had commented that phthisis frequently complicated diabetes. In 1883, Windle autopsied 333 known diabetic subjects and observed pulmonary tuberculosis in more than 50% of them[12]. In 1934, a treatise on the association between the two diseases was written by Howard Root[13] who reported that 2.8% of 1373

hospitalised diabetics had pulmonary tuberculosis. Of the 750 juvenile diabetics, 1.6% had tuberculosis as compared to 0.12% among school children. After studying the association between diabetes and tuberculosis, he made the following observations:

(i) Tuberculosis occurred ten times more frequently in juvenile diabetics.

(ii) In 85% of the patients, tuberculosis had developed after the onset of diabetes.

(ii) The occurrence of pulmonary tuberculosis increased with the duration of diabetes.

Hence, Root concluded that a diabetic patient appeared doomed to die of pulmonary tuberculosis if he succeeded in escaping diabetic coma and postulated that diabetic patients tend to contract tuberculosis but the reverse was rare. The Philadelphia Diabetic survey revealed that 8.4% of the 3,106 diabetics had pulmonary tuberculosis as compared to 4.3% of the 71,767 presumably healthy industrial workers[14]. Tuberculosis was present in 17% of the diabetics who had had the disease for more than 10 years compared to 5% in the diabetics with less than 10 years of the disease. A higher prevalence of tuberculosis was found in diabetics requiring more than 40 units of insulin per day. Some of the later studies, done in developed countries have failed to demonstrate an epidemiological association between TB and DM.[15,16] Perhaps, this is largely due to the low prevalence of tuberculosis in these areas. However, in countries like India, diabetes remains one of the most important risk factors disposing towards tuberculosis, along with malnutrition, alcoholism and HIV infection. A study carried out at the Regional Institute of Medical Sciences, Imphal, found the

prevalence of pulmonary tuberculosis in people with diabetes to be 27 per cent by radiological diagnosis and 6 per cent by sputum positivity.[17] In a study in Mumbai, tuberculosis was found to be the most commonly occurring concomitant illness in DM patients with 5.9 per cent of individuals being co-morbidly affected in a cohort of over 8000.[18]

Could the relationship between DM and TB be bi-directional?

Though the association between DM and TB is undoubtedly certain, clinicians were often unable to determine whether DM caused TB or whether TB led to the clinical manifestation of DM.[13,14,19-21] Engelbach and Nichols suggested that not only could having diabetes increase an individual's likelihood of developing TB but that having TB could lead to the presentation of diabetes.[22,23] Studies have shown both a high prevalence of diabetes and of impaired glucose tolerance (IGT) in patients with TB. However, it is often not known if DM or IGT were present prior to TB infection as a high proportion of people with diabetes and especially IGT are unaware of their glycemic status. Some studies have noted a normalization of glucose levels after TB treatment in individuals who had developed hyperglycaemia. This poses the question as to whether it is the active disease or the treatment for it that causes these metabolic anomalies.[24] lt is also known that tuberculosis, as with other infections, complicates diabetes management and that some of the TB treatment regimes which include isoniazid or rifampicin have hyperglycaemic effects.[25, 26]

Biological plausibility for the association

DM is known to cause immune dysfunction and moderate suppression of the immune system.[27] Specifically, DM has been shown to suppress cell mediated

immunity by decreasing the levels of leucocytes and Polymorphonuclear Neutrophils (PMNs) which produce cytokines and carry out phagocytosis. A reduced T-helper1 (Th1) cytokine response level is also seen amongst diabetic individuals.[27,28] This immune dysfunction is detrimental to the immune response against TB. Th1 cytokines are vital in the control and inhibition of *Mycobacterium tuberculosis* bacilli. For example, interferon gamma (IFN-γ) is important for combating microbial infections and both IFN-γ and tumor necrosis factor alpha (TNF-α) activate macrophages. Activated macrophages release Reactive Oxygen Species (ROS) and free radicals such as nitric oxide which are essential for the control of infection, including TB.[29] Not only are macrophages the primary site of TB infection but these cells also instigate the main immune response to TB.[30] Macrophage function is found to be inhibited in individuals with diabetes, with production of ROS, and phagocytic and chemotactic functions being impaired. All of these immune processes are important for TB clearance and, as such, diminution of these gives a very plausible pathway for the increased risk of TB infection.[27,28]

There have also been some plausible mechanisms highlighted in the literature through which TB infection could cause hyperglycaemia. Acute severe stress is an important cause of the development of impaired glucose tolerance. Fever, protracted inactivity and malnutrition stimulate the stress hormones epinephrine, glucagon, cortisol and growth hormone, which acting synergistically raise the blood sugar level in excess of 200 mg%.[31] Plasma levels of Interleukin - 1 (IL-1) and TNF alpha are also raised in severe illness which can stimulate the anti-insulin hormones.[32] Age, co-existent illnesses and alcoholism also influence

the host response. Serum levels of adrenocortico-tropic hormone, cortisol and T_3 have been found to be decreased in patients with tuberculosis.[33] Clinical and sub-clinical hypoadrenalism has been described frequently in these patients.[34] These abnormalities make the patient's ability for a stress response doubtful. The endocrine function of pancreas has also been found to be adversely affected in severe tuberculosis. In a report of 331 autopsied cases of amyloid, ages ranging from 16 to 87, Schwartz observed tuberculous lesions somewhere in the body in practically all of them, usually from childhood infection, but more specifically amyloidosis of the pancreas in 224 cases. Moreover, most of those diagnosed as diabetic prior to death showed intense islet cell amyloidosis and Schwartz hypothesized that once amyloidosis of the pancreatic islet cells hit a critical mass, the result was diabetes mellitus.[35]Thus, according to Schwartz, most cases of pancreatic amyloidosis, as well as the inflammatory infiltrate of the islet cells characteristic of Juvenile diabetes, ought to be considered an immunopathy induced by tuberculosis. DM was easy enough to pick up with routine laboratory tests whereas TB being insidious in nature, often took a longer time to be discovered. Another study showed a higher incidence of chronic calcific pancreatitis in patients with concomitant diabetes and tuberculosis[36] leading to an absolute or relative insulin deficiency state. Yet another study showed that a family of fatty-acid-transporter proteins in the tubercle bacillus caused dysregulation of hepatic uptake of long chain fatty acids (LCFAs) which are an important source of energy for most organisms and also function as blood hormones regulating hepatic glucose metabolism.[37] In 1990, a landmark article appeared in the proceedings of The National Academy of Science which claimed

that insulin-dependent juvenile diabetes, all along thought to be from ‘‘autoimmune’’ destruction of the pancreatic islet beta cells, had been shown to be caused, in mice, by an antigen cross-reactive and related to a heat shock protein found in Mycobacterium tuberculosis.[38] Heat Shock Protein 70 (HSP-70) has been found in every bacteria, but not so for HSP-65, which is specific for Mycobacterium tuberculosis. Onset of beta-cell destruction was caused by lymphocytes which were originally produced to destroy and rid the body of HSP-65, a phenomena which did not occur when HSP-70 was used. Some weeks later antibodies to HSP-65 were formed, along with anti-insulin antibodies leading to overt insulin-dependent diabetes.

Issues related to the co-morbidity

DM and TB medications: There is evidence that rifampicin is metabolised poorly by diabetics. One small study of 17 TB patients revealed a 50 per cent reduction in active rifampicin metabolites in individuals with coexistent diabetes. Additionally, the presence of rifampicin reduced the effectiveness and concentration of nearly all diabetes medications tested.[39] Several possible explanations for the reduction in rifampicin levels have been suggested, including poor absorption of the medication, competitive enzymatic metabolism, and an increase in the body mass index (and volume of distribution) in the diabetic population. Surprisingly, despite the possible reduction in active rifampicin metabolites in diabetic patients with TB, there has been little evidence of significant treatment failure with rifampicin-based regimens.

Diabetes and hepatotoxicity during TB treatment: A recent analysis examined the issue of hepatotoxicity in diabetic patients undergoing treatment for active

TB. After considering several confounding variables, the authors found a 50 per cent increase in risk for hepatotoxicity in patients treated for TB who have coexistent DM.[40]

Diabetes and delayed smear conversion: Several studies show a prolonged period of smear positivity in diabetic patients with TB. The typical length of time for smear conversion was one to three weeks longer than for non-diabetics.[41] It is unclear if the prolonged smear positivity is due to an initial higher burden of TB (cavitary disease), poorly absorbed TB medications (i.e. rifampicin), or slightly higher rates of drug resistance in diabetics.

Diabetes and TB recurrence: While some studies have determined an increase in recurrence rates for diabetics with TB, several others have not found an association. However, two recent reviews showed an increase in smear positivity and cavitary disease at presentation to be associated with higher rates of recurrence which prompted several regions in the Pacific to increase treatment to 9 months (2+7) in diabetics with cavitary disease or prolonged sputum smear positivity.[42]

Diabetes and death during TB treatment: Recent large reviews have indicated that the risk of death during treatment increases 3 to 7 times in the diabetic with TB.

Diabetes and drug-resistant TB: Studies have revealed an association between diabetes and drug-resistant TB, including an outbreak in New York City, as well as a recent survey in Texas and Mexico. Other evaluations did not show a relationship between diabetes and drug-resistant TB.

A case control study done in Indonesia between 2001 and 2005 found that diabetes was present in 60 of 454 TB patients (13.2%) and 18 of 556 (3.2%) control subjects giving an Odds Ratio (OR) of 4.7. Impaired FBG was present (3.3%) of TB patients and 0.9% of controls, OR - 4. The study concluded that diabetes mellitus is strongly associated with TB in young and non-obese subjects.[43]

A cohort study was done in Hong Kong to assess the effects of diabetes mellitus and diabetic control on tuberculosis risk. It prospectively followed up 42,116 clients aged 65 years or more from 2000-2005 for development of tuberculosis. Diabetes mellitus was found to be associated with a modest increase in the risk of active, culture-confirmed, pulmonary (with or without extra-pulmonary involvement) with adjusted hazard ratios of 1.77 (95% confidence interval- 1.41- 2.24). The study also revealed that diabetic subjects with Glycosylated hemoglobin (HbA1c) < 7% at enrollment were not at increased risk.[44]

A cross sectional study was done in Bahawalpur, Pakistan in 2001 with the aim of finding out the prevalence of pulmonary TB among diabetics and comparing it with prevalence in non- diabetics. The study observed a 7.5 % higher prevalence of TB in diabetics as compared to non diabetics which was found to be statistically significant. The study thus recommends that diabetics should be screened actively for TB.[45]

A retrospective study done on a cohort of 2,841 TB patients in Taiwan from 1996-1993 showed prevalence rate of diabetes was 16.9%. The risk of developing DM was 4.2 times higher in TB patients than in the general

population. Another important observation of the study was that 16.3 % of the diabetics with TB had lower lung involvement in contrast to 0.8 % in non diabetics. The study recommended routine screening for DM among TB patients and emphasized that a strong suspicion of DM be made in patients with lower lobe TB.[46]

A cross sectional study conducted during the period 2006-2008, in the Texas- Mexico border on 233 TB patients found the prevalence of diabetes to be 39% (4% previously undiagnosed) in Texas and 36% (19%) in Mexico. Diabetics were at higher risk of contracting TB than non diabetics.[47]

A case control study done in California among 5,290 cases of TB and 37,366 controls during 1991, found that DM was an independent risk factor for TB. The association was higher among Hispanics (OR- 2.95) than non-Hipanics. Among Hispanics aged 25-54, the estimated risk of TB attributable to DM was 25.2% equivalent to that attributable to HIV infection.[48]

In a study conducted in Tanzania among 506 patients with sputum positive pulmonary tuberculosis; the prevalence of diabetes mellitus was found to be 6.7% confirmed by doing OGTT. Impaired glucose tolerance (IGT) was seen in 16.2% subjects. For comparison, glucose tolerance was done in 693 members of an urban community not affected with tuberculosis which showed the prevalence rates of diabetes and IGT as 0.9% and 8.8% respectively. Diabetes was therefore at least four times as common in the tuberculosis patients ($p < 0.001$), and IGT twice as frequent ($p < 0.0001$).[49]

Another six year retrospective study from 5049 TB patients from South Texas and northeastern Mexico between 1988-1994,found diabetes self-reported

by 27.8% of Texan and 17.8% of Mexican TB patients, significantly exceeding national self reported diabetes rates for both countries. Diabetes co morbidity substantially exceeded that of HIV/AIDS. Patients with TB and diabetes were older, more likely to have haemoptysis, pulmonary cavitations, be smear- positive at diagnosis, and remain positive at the end of the first or second month of treatment. The impact of type 2 DM on TB is underappreciated, and in the light of its epidemic status in many countries, it should be actively considered by TB control programmes, particularly in older patients.[50]

A retrospective case control study conducted in Turkey between 1997-2003 which aimed to determine whether or not DM alters the treatment outcomes, demographic, clinical or radiological presentation of TB revealed that cavity formation and atypical localization were more often found in diabetics. The prevalence of DM among TB patients was 7.3%. The duration of treatment and the rate of drug resistance was more with diabetics, though the cure rates were same with both the groups.[51]

A cross-sectional study conducted among 260 adult patients with TB in Uganda during 2011-2012 observed 8.5 % prevalence of DM of which only 1.9% patients had a known diagnosis of diabetes mellitus at enrollment. Majority (90.9%) of the study participants with TB-DM co-infection had type 2 DM. At bivariate analysis, raised mean serum alanine transaminase concentrations of ≥80 U/L were associated with DM (OR-6.1) and paradoxically HIV co-infection was protective of DM (OR-0.32).[52]

A case-control study conducted in an urban population in Tanzania during 2006-2009 with 803 cases and 350 controls observed that the prevalence of

diabetes was 16.7% among TB patients as compared to 9.4% among non-TB patients. Diabetes was strongly associated with TB (OR-2.2). However; the association depended on HIV status showing stronger association among HIV uninfected (OR 4.2) compared to HIV infected (OR-0.1). Hence the authors suggested that diabetes is a risk factor for TB in HIV uninfected, whereas the association in HIV infected patients needs further study.[53]

A cross-sectional study was conducted in Northeast Ethiopia in 2012 among 225 diabetic patients suspected of TB. Sputum specimens were collected from the study participants and examined for acid-fast bacilli. The prevalence of smear positive TB was 6.2% in TB suspected diabetic patients, which is higher compared to the general population (0.39%). Patients with a previous history of contact with TB patients, as well as those who had prolonged diabetes, were more prone to have pulmonary TB. Therefore the study recommended screening of diabetic patients for TB infection during follow-up.[54]

A study done in China in 2012 observed that of the 8023 TB patients screened 12.4% patients with DM were identified, of whom 9.7% had a known diagnosis of DM and 2.9% was newly diagnosed. In addition, 7.8% persons had impaired fasting glucose (FBG 6.1 to <7.0 mm). Prevalence of DM was significantly higher in patients in health facilities serving urban populations (14.0%) than rural populations (10.6%) and higher in hospital patients (13.5%) than those attending TB clinics (8.5%).[55]

A retrospective cohort study was conducted in Maryland during 2004-2005 among patients with active, culture confirmed TB to determine the prevalence of DM in them and to compare treatment outcomes in TB patients

with versus without DM. The study found 14 % prevalence of DM among TB patients. DM-TB patients more commonly had pulmonary disease (90% vs 75%), were older (mean age 57yrs vs 40 yrs) and were slightly heavier than those without DM. Diabetic patients had 2 times higher odds to death than the non-diabetics. Time to sputum or culture conversion and the rate of treatment failure between the two groups was not significant. The study suggested that TB patients be screened for DM.[56]

A prospective study done in Indonesia from 2000 to 2005 screened 737 pulmonary TB patients for DM and found the prevalence to be 14.8%. These patients were followed up during TB treatment to study the clinical characteristics and outcome and were compared with TB patients who did not have DM. On presentation, diabetic patients with TB had more symptoms and after 2 months, results of sputum microscopic examination were more often positive in diabetic patients (18.1% vs. 10.0%). After 6 months, 22.2% of cultured sputum specimens from diabetic patients were positive for *Mycobacterium tuberculosis* (adjusted odds ratio, 7.65; p.004). The study concluded that DM has a negative effect on the outcome of TB treatment and the underlying mechanisms for the different response to treatment in diabetic patients with TB must be explored. Screening for DM and subsequent glycemic control may improve the outcome of TB treatment.[57]

A retrospective study done in Texas-Mexico from 1996-2003 observed that 5.6% of the TB patients had MDR TB and this was significantly associated with DM (OR-2.1). Though patients with DM were consistently more compliant with Directly Observed Treatment Short Course (DOTS) therapy than patients

without DM (OR- 2.4), drug resistance was more common in them probably because of impaired immunity which increases susceptibility to infection with resistant strains.[58]

A matched case control study with 189 patients done in South India during 2001-2003, found a strong association for TB in patients with DM with or without hypertension and coronary heart disease with an OR of 2.44. Other significant risk factors were low education level (OR- 0.30) and not having separate kitchen (OR- 3.26). The study reflected the complex interaction between non-communicable disease, urbanization and a changing economic climate in India.[59]

A study conducted in 2000 found that 18.4% (12.5% to 29.9%) of people with pulmonary TB (both smear-positive and smear-negative) had diabetes, and that in the smear positive group diabetes prevalence was 23.5% (12.1% to 44%). The study suggested that a substantial proportion of incident TB in India was attributable to diabetes (14.8% of pulmonary TB and 20.2% of smear-positive cases). Estimates of the urban/rural distribution of the annual risk of TB infection showed that, on average, smear-positive TB incidence in India is 69.2% higher in urban compared with rural areas. The researchers opinioned that increased prevalence of diabetes in urban areas has important implications for tuberculosis control.[60]

A systematic review and meta analysis of 13 observational studies based on PubMed and EMBASE database found that DM was associated with increased risk of TB regardless of study design, background TB incidence, or geographic region and population. Cohort studies showed a relative risk of 3.11 (95% CI

2.27–4.26) and case-control studies gave an odds ratio ranging from 1.16 to 7.83. So the authors concluded that people with DM may be important targets for interventions such as active case finding, treatment of latent TB and efforts to diagnose and treat DM in patients with TB may have a beneficial impact on TB control.[61]

A study done by the research committee of the Tuberculosis Association of India in 1987 investigated 935 TB patients, 169 patients with non- tubercular chest diseases and 192 healthy controls for evidence of undetected DM. The prevalence of unknown diabetes in the 3 groups was found to be 9.7 %, 8.9% and 15.6% respectively. The study also found a much higher prevalence above the age of 40 years and no significant difference in the prevalence of diabetes with respect to extent and severity of pulmonary disease.[62]

A retrospective study done in Kashmir from 1987-1992 among 729 patients to find the incidence and pattern of infections in DM revealed that TB was the second commonest infection (20.1 %) encountered after urinary tract infections (28.6%).[63]

A cross-sectional study done in Kerala in 2011 to estimate the prevalence of DM among TB patients screened a state-wide representative sample of TB patients for glycosylated hemoglobin (HbA1c). Among 552 TB patients screened, 243 (44%) had DM of which 128 (23%) had previously known DM and 115 (21%) were newly diagnosed - with higher prevalence among males and those aged 50years. The number needed to screen (NNS) to find one newly diagnosed case of DM was just four. Of the TB patients with previously known DM, 107 (84%) had HbA1c ≥ 7% indicating poor glycemic control. The study

concluded that nearly half of TB patients in Kerala have DM, of which half were newly-diagnosed.[64]

A cross sectional study was done to find out the prevalence of DM among TB patients in Tamil Nadu in 2011. Among the 827 TB patients DM prevalence was 25.3% and that of pre-diabetes was 24.5%. Risk factors associated with DM among TB patients were age, positive family history of DM (OR-3.08), sedentary occupation (OR-1.69) and BMI ≤ 18.5 kg/m2 (OR-2.03) and for pre-diabetes, risk factors were age, waist circumference ≥ 90 cm (men) and ≥ 80 cm (women) and smoking (OR-1.92). DM risk was higher among pulmonary TB (OR-3.06) especially sputum positive, than non pulmonary TB.[65]

A study done in India in 2012 to assess the feasibility of screening patients with TB for DM within the routine healthcare setting across the country screened 8269 TB patients diagnosed and initiated on treatment. Prevalence of DM was 13%. Of these 8% had a previously known diagnosis of DM and 5% were newly diagnosed. There was a higher prevalence in patients screened from tertiary care hospitals (16%) than from tuberculosis units (9%) ($P < 0.001$) and amongst those from South India (20%) than from North India (10%) ($P < 0.001$). The screening and referral process worked well although significantly more patients with DM diagnosed in hospitals were referred to DM care (96%) than patients diagnosed in tuberculosis units (92%) ($P < 0.05$).[66]

Consultation meeting on tuberculosis and diabetes mellitus

In order to establish the current knowledge base, identify gaps and recommend future course of action, including establishing an agenda for future

research and development of policy for action on TB and DM co morbidity, the International Union Against Tuberculosis and Lung Disease (The Union), the World Diabetes Foundation (WDF) and the WHO Stop TB Department undertook, in January 2009, a series of consultations.[67] Based on these consultations, it was realised that an additional literature review was needed to:

1) Update any new evidence regarding the association of DM with active TB as well as with latent TB infection
2) Establish the need, if any, for screening DM and TB patients for the other condition to facilitate early detection of the co-morbidity as well as to assess any impact of chemoprophylaxis in preventing active TB in DM patients
3) Assess the impact of DM on the clinical and programmatic management of TB, with a focus on sputum smear/culture conversion, TB treatment outcome, recurrent TB, pharmacokinetic interactions between DM and TB medications and anti tuberculosis drug resistance
4) Identify existing evidence, if any, of the effect of DM prevention on TB burden.

Thus an additional systematic review and meta- analysis was undertaken from May to August 2009 by Professor Megan Murray and her team (Department of Epidemiology, Harvard School of Public Health). A consultation meeting involving the experts who reviewed the report took place at The Union Headquarters in Paris on 6 and 7 November 2009.

OBJECTIVES OF THE CONSULTATION MEETING

1) To review, discuss and endorse the findings of the systematic review

2) To identify knowledge gaps and identify a prioritized research agenda
3) To suggest future courses of action to address the potentially dangerous public health threat posed by the rising dual burden of DM and TB, especially in the developing countries, and to recommend actions to promote and improve collaboration between TB and DM prevention, care and control services.

RECOMMENDATIONS OF THE CONSULTATION MEETING

The consultation meeting identified four main sets of recommendations.

1) **Collaboration between TB and DM care and control initiatives**

• Ministries of health, technical agencies, funding agencies and donors should recognise the link between DM and TB and encourage closer collaboration between national TB programmes and stakeholders involved in national DM prevention and care.

• National TB programmes and stakeholders involved in national DM prevention and care should develop collaborative activities in the following areas:

1) Incorporation into national guidelines the relevant aspects of screening, diagnosis, management and prevention of DM and TB respectively
2) Joint planning and training
3) Integrated care and control services
4) Coordinated supervision, monitoring and evaluation, and surveillance
5) Research
6) Development of undergraduate training curricula on TB and DM

2) Screening for active TB among people with DM

• In countries with high TB burden, patients with DM should be routinely screened for TB symptoms and recent exposure to TB as part of regular clinical check-ups. At a minimum, people with persistent cough (>2 weeks) should be screened for TB following the standard diagnostic algorithm used in the country.

• The following approaches may be considered, depending on the prevalence of TB and DM, the TB case detection gap and health care resources in a given setting:

— Initial screening for active TB with additional diagnostic tests such as X-ray, culture, abdominal ultrasound, etc.

— Screening on wider indication based on additional TB risk markers like

1) Recent contact with people with active TB

2) Symptoms suggestive of TB (cough of any duration, weight loss, fever, etc.)

3) Poor diabetes control

4) Migrants from high TB incidence areas

5) Other TB risk factors (smoking, alcohol abuse, malnutrition etc.)

3) Screening for DM among TB patients

• People with newly diagnosed TB should be screened for DM, at least in countries with a medium to high prevalence of DM, and the results of screening should be registered in the TB treatment register.

• While waiting for better evidence concerning the appropriate screening method and timing of screening, it is advisable to screen with either random or fasting blood glucose, urine glucose, and/or HbA1C at the time of TB diagnosis, and to repeat a positive diagnostic test after 3 months of TB treatment.

4) Management of TB and DM co-morbidity

• Among patients with DM and active TB, all aspects of treatment, case management, monitoring of side effects and complications, patient support and health education for both TB and DM should be optimised, as per national guidelines and/or internationally accepted best practice which is suitable to available resources.

• Appropriate cross-referral of TB and DM cases should be ensured, while integrated approaches for diagnosis, management and prevention should be explored.

• Among patients with DM and active TB, DM health education and behaviour change messages and interventions should be part of the health education delivered as part of routine encounters with health workers for TB management.

• The applicability of the DOTS model (political commitment, quality assured diagnosis, standardized treatment with adequate patient support, ensured drug supply, and standardized monitoring and evaluation) should be explored for the management of DM.

METHODOLOGY

The present study was conducted in three primary health centres (PHC) - Handignur, Vantamuri, Kinaye; three urban health centres (UHC) - Ram Nagar, Asok Nagar, Rukmini Nagar which are the field practice areas of Department of Community Medicine, Jawaharlal Nehru Medical College, Belgaum and in RNTCP unit, Government District Hospital Belgaum. As per RNTCP guidelines for every one lakh population there exists one Designated Microscopic Centre (DMC). PHC Handignur and PHC Vantamuri come under DMC Vantamuri (Rural). PHC Kinaye comes under DMC Uchgaon. All three UHCs come under Vantamuri (Urban). Government District Hospital being a tertiary care centre is a DMC by itself.

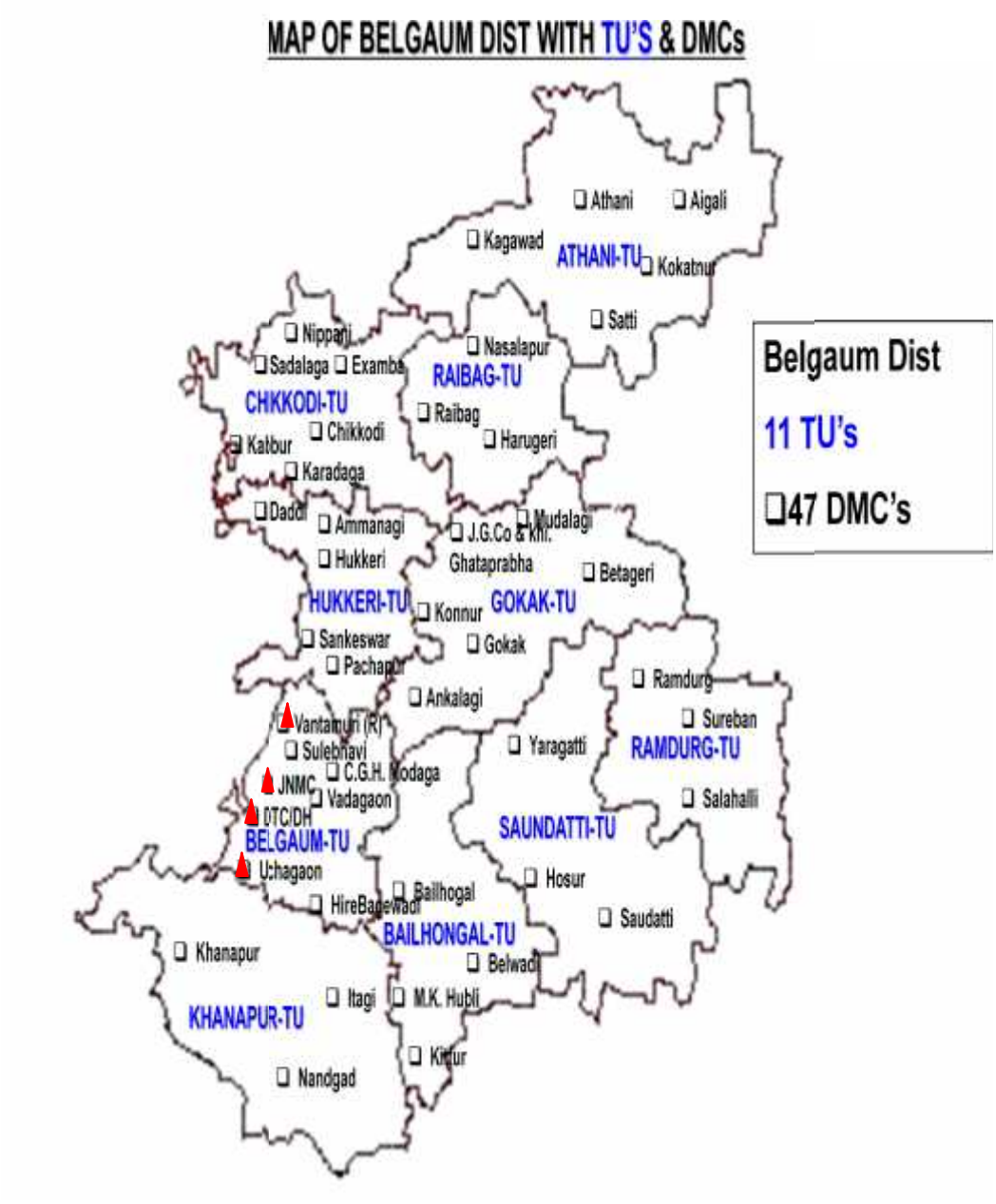


Fig:1 Map Showing the DMC of the study areas in red triangle

Study design: A cross-sectional study.

Study period: One year – From January 2012 to December 2012.

Sample size: By taking the prevalence of DM in tuberculosis as 19%, [60] the sample size was calculated using the formula:

$$\mathbf{n = 4pq / d^2}$$

n =sample size

p = prevalence of DM in TB

q = 100-p

d = relative error = 3.8 (20 % of p)

Total sample = 426

≈ 430

Source of data: The patients diagnosed as tuberculosis and registered under RNTCP for treatment in the study areas.

Ethical Clearance

The present study was approved by K.L.E University's Jawaharlal Nehru Medical College Institutional Ethics Committee on Human subjects' Research. (Annexure I)

Method of collection of data:

RNTCP registers maintained at the Primary Health Centres, Urban Health Centres and Government District Hospital, Belgaum was used to identify the patients. After obtaining the consent, a pretested questionnaire (Annexure II) was used to collect information regarding socio demographic details and habitual risk factors viz., smoking, alcohol consumption, other forms of tobacco use; family history of TB and DM, educational and occupational status, and monthly income. Type of TB, HIV status and category of TB treatment were also recorded. The patients were clinically examined by the investigator and anthropometric measurements viz., height, weight, and waist circumference were measured by standard procedure. Screening for diabetes was done by estimating the Fasting Blood Glucose (FBG) in capillary blood, using glucose-oxidase strips read in a reflectance meter (Accu check glucometer system).Those who showed an FBS value of ≥ 110mg/dl were subjected to Oral Glucose Tolerance Test (OGTT). After an overnight fast of 8-14 hours fasting venous sample was collected. A 75 grams glucose solution was administered, and venous blood glucose was measured 2 hours later. Diagnosis of diabetes was based on previous history of diabetes or on WHO criteria for the classification of glucose tolerance.[68]

Inclusion Criteria:

1. All patients diagnosed as TB and registered under RNTCP

Exclusion Criteria:

1. Pregnant women to exclude possible gestational diabetes mellitus
2. Age ≤ 15 years.

Data Entry:

Codes were prepared for each options of the questionnaire. Data was entered in excel sheet to prepare a master chart. SPSS version 18.0 software was used for analysis of the data. Tables and graphs were prepared by using Microsoft Windows 2007 software.

Data Analysis:

- Socio-demographic variables were analyzed and expressed as rates.
- Chi square test was used to compare the clinical and socio- demographic profile of patients with co- existent diabetes and tuberculosis with patients of tuberculosis alone.

Definition of study variables

Age: Age was recorded to the nearest completed years.

Religion: The subject's religion was noted and was grouped as Hindu, Muslim, and Others (Christians, Jains, Buddhists, and Parsis etc)

Occupation:[69]

- Professional- This group consists of occupations which involve education level graduation and above. The individuals belonging to this group are doctors, engineers, etc.
- Semi professional -This group consists of occupations which involve education level post high school and above. The individuals belonging to

this group are high school teachers, commission agents, junior engineers etc.

- Clerical, Shop owners, Farm owners; etc- This group consists of persons with some training in arithmetic and also in reading and writing. Here the work is essentially of a repetitive type. They have some general education and some training to manage routine work. The persons belonging to this group are clerk, typist, accountant, primary school teacher, shop keeper, farm owners, salesman, insurance agents etc.
- Skilled worker: They have got a long training in a rather complicated work. This group consists of masons, carpenter, mechanic, radio serviceman, car drivers, telephone operators etc.
- Semi skilled workers: In this category, the person needs some training to do their routine jobs efficiently. The individuals belonging to this group are laboratory attenders, library attenders etc.
- Unskilled worker: This group consists of all the persons whose work involves neither education nor training such as watchman, peon, coolie, domestic servant, etc.
- Unemployed: Persons who are unemployed irrespective of their general and professional education or training are grouped into this category
- Housewife/ Homemaker

Educational status:[70] The subjects were asked about their highest level of completed education and were grouped into following categories.

- Illiterate - A person who cannot read and write.
- Primary school – Person who has studied up to 7^{th} standard.

- High school – Person who has studied up to 10th standard
- Pre-university / Diploma – Person who has studied up to PUC 2nd year or a Diploma Course.
- Graduate or Post graduate– Person who has obtained any Graduate degree or Post graduate degree.

Type of family:[71]

- Nuclear family: Married couples, along with their dependent children living in the same house.
- Joint or extended family: Many married couples and their children who are living in the same household. All males are blood relatives and all females of the family are related by either marriage or blood relation.
- Three generation family: Married couple with married children and their kids (three generations) related to each other by direct descent and living together.
- Broken family: One where, the couple have separated, or where death has occurred for one or both the spouses.

***Socio-economic status*:**

Information regarding per capita income (in Rupees / month) was collected and socio-economic status was classified using Modified B G Prasad's classification for the study period (2012)[72] and it was calculated by multiplication factor with 1961 Prasad's classification values.

Average consumer price index [73] for year 2012 = 969

Modification was done with the aid of multiplication factor (M.F), which was obtained as below:

$$\text{M.F.} = \frac{\text{Average consumer price index for the study period (2012)}}{100} \times 4.93$$

$$= 969 /100 \text{ x } 4.93 = 47.77 \approx 48$$

Social-economic class.	**B.G. Prasad's classification 1961 (per capita income in Rs/month)**	**Modified B.G. Prasad's classification In study period 2012 (per capita income in Rs/month)**
I	≥100	Above 4800
II	50—99	2400 – 4799
III	30-49	1440 – 2399
IV	15-29	720 – 1439
V	≤15	Below 720

Housing standards

Type of house:[74]

- Pucca house: is one which has walls and roof made up of the following material. Wall material – burnt bricks, stones (packed with lime or cement), cement concrete, timber, ekra etc. Roof material- tiles, GCI (Galvanized corrugated iron) sheets, asbestos

sheets, Reinforced Brick Concrete (RBC), Reinforced Cement Concrete (RCC) and timber.

- Kutcha house: The walls and/or roof of which are made up of materials other than those mentioned above, such as un-burnt bricks, bamboos, mud, grass, reeds, thatch, loosely packed stones.
- Semi – pucca house: a house that has fixed walls made up of pucca material but roof is made up of material other than those used for pucca house.

Overcrowding:[71] Overcrowding is expressed as the number of persons divided by the number of rooms. It is called overcrowding if these standards are exceeded.

1 room – 2 persons

2 room – 3 persons

3 room – 5 persons

4 room – 7 persons

5 or more rooms – 10 persons (additional 2 persons for each further room)

Symptoms of Tuberculosis: Patients were asked for the cardinal symptoms of tuberculosis viz: cough with expectoration, fever, hemoptysis, dyspnea, night sweats, weight loss and loss of appetite.

Symptom scoring: A symptom score was calculated on the basis of presence of cough, hemoptysis, dyspnea, fever, night sweats, weight loss and loss of appetite (one point for each item). Patients with a symptom score ≥ 4 were classified as highly symptomatic.[57]

Tobacco use:[75] For the assessment of history of use of tobacco in any form (smoking/smokeless) period of recall was considered for the past one year

Smoking tobacco:

- Smokers: Subjects those who had smoked in the past or smoking at present were considered as "smokers".
- Current smoker: The person who smoked beedis or cigarettes at least for the last one year.
- Past smoker: The person who smoked beedis or cigarettes earlier but left smoking for the last one year.
- Non Smokers: Subjects who had never smoked any form of tobacco (Cigarettes/Beedi) were considered as "non smokers".

Smokeless tobacco use:

- Smokeless tobacco user: Subjects those who had used smokeless tobacco in the past or using at present were considered as "smokeless tobacco user".
- Current use of smokeless tobacco: The person who used any form of smokeless tobacco products (Snuff, Gutka, Chewing tobacco, etc.,) at least for the last one year.
- Past user of smokeless tobacco: The person who used smokeless tobacco but stopped using for the last one year.

- Non user of smokeless tobacco: Subjects who had never used smokeless tobacco in any form were considered as “non users”.

Alcohol consumption:[76] For the assessment of alcohol consumption, period of recall was considered for the past one year.

- Alcoholic: A person who has been taking alcohol at least 30 ml per day for at least six months preceding the survey.
- Present Alcoholic: The person who had consumed alcohol for the last one year.
- Past Alcoholic: The person who had consumed alcohol earlier but left consuming for the last one year.
- Non Alcoholic: Subject who had never consumed alcohol were considered and kept in the category of “Non Alcoholic”.

Type of Diet: The subject’s dietary habit was asked and was grouped as follows;

- Vegetarian: diet derived from plants, with or without eggs or dairy.
- Ovo-vegetarian: vegetarian diet which includes eggs but not dairy products (lacto-vegetarian diet includes dairy products but not eggs, and an ovo-lacto vegetarian diet includes both eggs and dairy products).
- Non-vegetarian: consist largely of vegetarian foods, but may include fish or poultry, or sometimes other meats, on an infrequent basis.

Physical Activity:[76] Physical activity was assessed in two domains and classified as sedentary, moderate and vigorous activities in each domain.

- **Work related / Job related physical activity:** (paid and unpaid work- inside and outside home)

    1) Work involving, mostly sitting or standing, with walking for not more than 10 minutes at a time was graded as sedentary work
    2) Work involving moderate-intensity activity, like brisk walking, carrying light loads for at least 10 minutes at a time was graded as moderate work.
    3) Work involving vigorous activity like heavy lifting, digging or other work for at least 10 minutes at a time was graded as vigorous work.

- **Leisure time physical activity:**

    1) Recreation, sport or leisure time involve mostly sitting, reclining, or standing, with no physical activity lasting more than 10 minutes at a time was graded as sedentary during leisure.

    2) Any moderate intensity activities like brisk walking, cycling, playing games, for at least 10 minutes at a time was graded as moderately active during leisure.

    3) Any vigorous activities like running or strenuous sports, weight lifting for at least 10 minutes at a time was graded vigorously active during leisure.

Family history of DM: History of DM among the first degree relatives ie; parents and siblings of the participants were enquired.

Previous history of DM or a known case of DM: A patient giving either a medical history of diabetes diagnosed by a physician or if the person is on oral hypoglycemic agents or insulin or both.

History of contact with TB case:[77] A contact is defined as living in the same household or in frequent contact with a source case who is sputum smear positive or culture positive for tubercle bacilli.

ANTHROPOMETRIC MEASUREMENTS

Height:[76] The subject was asked to stand straight without footwear, with heels, buttocks and back straight and arms hanging by side. The height was measured from head to heal. The coinciding reading was measured to the nearest 0.1 cm using a metallic measuring tape.

Weight:[76] Body weight was measured without any foot wear and with minimal clothing to the nearest 0.1 kilogram using a standard portable adult weighing machine, which was standardized periodically during the study. The scale was adjusted to zero before each session and weight was recorded in kilograms.

Body Mass Index (BMI):[78] As per the revised guidelines recommended by WHO, persons with BMI values of less than 18.5 were classified as "Underweight", 18.5 to 24.9 were classified as "Normal weight", 25 to 29.99 were classified as "over-weight" and 30 and above were classified as "Obese".

Body Mass Index was calculated as;

$$BMI = \frac{\text{Weight in Kgs}}{(\text{Height in Meter})^2}$$

Waist circumference (WC):[79] The measurement was made at the approximate midpoint between the lower margin of the last palpable rib and the top of the iliac crest and the subject stands with arms at the sides, feet positioned close together, and weight evenly distributed across the feet. Waist circumference > 80 centimeter for females and > 90 centimeter for males was considered to have abdominal obesity.

Disease classification under RNTCP [80]

Pulmonary tuberculosis:

Smear positive*:* A patient with one or two smears positive for Acid Fast Bacilli (AFB) out of the two sputum specimens subjected for smear examination by direct microscopy.

Smear negative*:* A patient with symptoms suggestive of TB with two smear examination negative for AFB, with evidence of pulmonary TB by microbiological methods (culture positive or by other approved molecular methods) or chest X-ray.

Extra pulmonary tuberculosis: TB of organs other than the lungs such as pleura, lymph nodes, intestine, genitor-urinary tract, joint and bones, meninges of the brain etc.

Guidelines to determine the type of patient [80]

New case: A patient who has never had treatment for TB or has taken anti- TB drugs for less than one month.

Treatment after default: A patient who received treatment for TB for a month or more from any source and returns for treatment after having defaulted i.e., not taken anti-TB drugs consecutively for two months or more and found to be smear positive. Default rate should be < 5%.

Failure: Any TB patient who remains smear positive at 5 months or more after initiation of treatment. Failure also includes a patient who was initially smear negative but who becomes smear positive during treatment.

Relapse: A TB patient who was declared cured or treatment completed by a physician and who reports back to the health facility and is now found to be bacteriologically positive.

Transferred in: A TB patient who has been received for treatment in a tuberculosis unit after starting treatment in another tuberculosis unit where he has been registered.

Transferred out: A patient who has been transferred to another tuberculosis unit.

Others: A patient who does not fit into any of the types mentioned above. The reasons for labeling a patient under this type must be specified in the treatment card and the TB registers.

Treatment regimens:[80]

Category I / New cases: Sputum smear positive

Sputum smear negative

Extra-pulmonary

Others

Category II / previously treated: Smear positive relapse

Smear positive failure

Smear positive treatment after default

Sputum results in microscopy:[80]

If the slide has	**No: of fields to be examined**	**Grading**	**Result**
No AFB in 100 oil immersion fields	100	0	Negative
1-9 AFB per 100 oil immersion fields	100	Scanty	Positive
10-99 AFB per 100 oil immersion fields	100	1+	Positive
1-10 AFB per oil immersion field	50	2+	Positive
More than 10 AFB per oil immersion field	20	3+	Positive

Case definition of HIV positive: A person is said to be HIV+ve when all 3serological tests Coombs, Tridot and Triline are positive.

WHO criteria for diagnosis of DM and other degrees of glucose intolerance[68]

Normoglycemia		FBG < 110mg/dl Or 2 hour post glucose load < 140 mg/dl
Pre diabetes	Impaired fasting glycemia (IFG)	FBG ≥ 110mg/dl and < 126 mg/dl And 2 hour post glucose load (if measured) < 140 mg/dl
	Impaired Glucose tolerance (IGT)	FBG < 126 mg/dl And 2 hour post glucose load ≥ 140 and < 200 mg/dl
Diabetes mellitus		FBG ≥ 126mg/dl Or 2hour post glucose load ≥ 200mg/dl

RESULTS

The present study was conducted in three primary health centres (PHC) - Handignur, Vantamuri, Kinaye and three urban health centres (UHC)- Ram Nagar, Asok Nagar, Rukmini Nagar which are the field practice areas of department of community medicine, Jawaharlal Nehru Medical College, Belgaum and in RNTCP unit, Government District Hospital Belgaum. A total of 437 TB patients registered under RNTCP from January 2012 to December 2012 from the study areas were included.

The data obtained was tabulated and analyzed under the following headings:

I. Socio-demographic variables

II. Prevalence of DM among TB patients

III. Comparison of socio demographic and clinical profile of patients with co- existent DM and TB with patients of TB alone.

I. Socio-demographic variables

Table 1. Distribution of the study participants according to Socio demographic variables

Socio- demographic variables		Number n =437	Percentage
Age (in years)	≤20	31	7
	21-30	112	25.6
	31-40	119	27.2
	41-50	97	22.2
	51-60	52	12
	61-70	26	6
Sex	Male	288	65.9
	Female	149	34.1
Religion	Hindu	348	79.7
	Muslim	79	18
	Others	10	2.3
Occupation	Professional	2	0.5
	Semi-Professional	13	2.9
	Clerk, etc.	35	8
	Skilled	60	13.7
	Semi-skilled	101	23.1
	Unskilled	89	20.4
	Unemployed	18	4.2
	Housewife	119	27.2

Socio- Demographic Variables		Number n =437	Percentage
Literacy	Illiterate	139	31.8
	Primary School	162	37.1
	Secondary School	97	22.2
	PUC	21	4.8
	Graduate	14	3.2
	Post Graduate	4	1
Marital status	Unmarried	54	12.4
	Married	346	79.2
	Widow/ Widower	26	5.9
	Divorcee/Separated	11	2.5
Family Type	Nuclear	139	31.8
	Joint	180	41.2
	Extended	81	18.5
	Broken	37	8.5
Socio- economic class	I	2	0.5
	II	32	7.4
	III	98	22.4
	IV	142	32.5
	V	163	37.2

In the present study; 25.6% of the participants belonged to the age group 21-30 years, 27.2% belonged to age group 31-40 years and 22.2% belonged to the age group 41-50 years. Majority of the subjects were males (65%) and followed Hindu religion (80%). Most of the study participants were engaged in skilled (13.7%); semi-skilled (23.1%) or unskilled work (20.4%). 27.2% were home makers and only 4.2% were unemployed. About 1/3 rd of the participants were illiterate and among the educated, majority has attended either till primary school (37%) or high school (22%). Around 75% of the participants lived in nuclear or joint family and except a few all belonged to socio economic class III, IV or V (92.1%).

II. Prevalence of DM among TB patients

Table 2. Distribution of the study participants according to FBG

FBG (mg/dl)	Study participants (n = 372)	
	Number	Percentage
≥110	141	37.9
<110	231	62.1
Total	372	100.0

Out of the total 437 TB patients; FBG was done on 372 patients; excluding 65 known cases of DM. Among the 372 patients who were screened with FBG, 141 (37.9%) patients showed FBG ≥ 110 mg/dl.

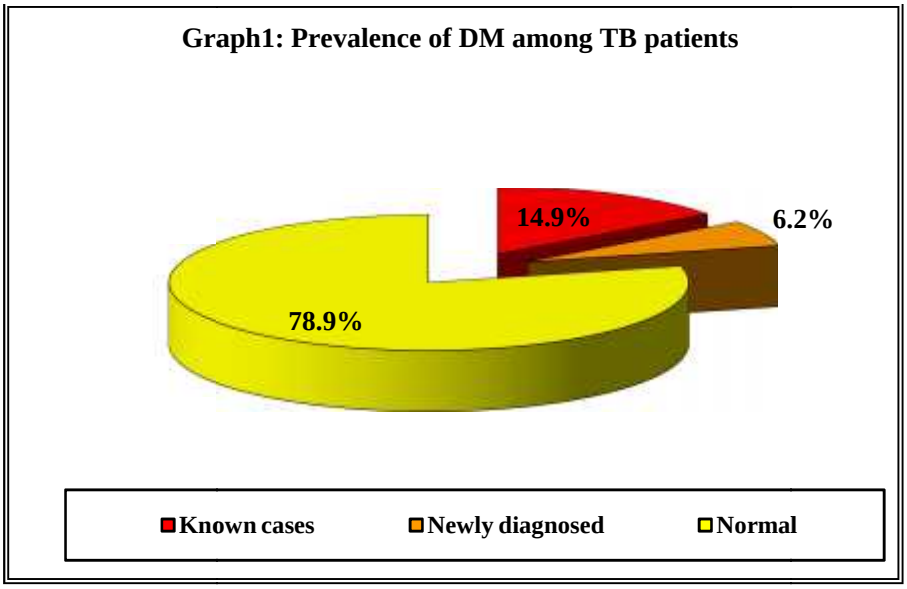
Table 3. Distribution of the study participants according to OGTT

OGTT Result	Study participants (n=141)	
	Number	Percentage
Normal	46	32.7
Pre diabetics	68	48.2
Diabetics	27	19.1
Total	141	100.0

All the 141 patients with FBG ≥ 110mg/dl were subjected to OGTT; of which 46 (32.7%) were normal, 68 (48.2%) were pre diabetic and 27 (19.1%) were newly diagnosed diabetics.

Table 4. Prevalence of DM among TB patients

Prevalence of DM	Study participants (n = 437)	
	Number	Percentage
Non diabetic	345	78.9
Known Cases of DM	65	14.9
Newly diagnosed DM	27	6.2
Total	92	21.1



Out of the 437 study subjects, 65 (14.9%) were known cases of DM and 27 (6.2%) were newly diagnosed to have DM. The total prevalence of DM was found to be 21.1%.

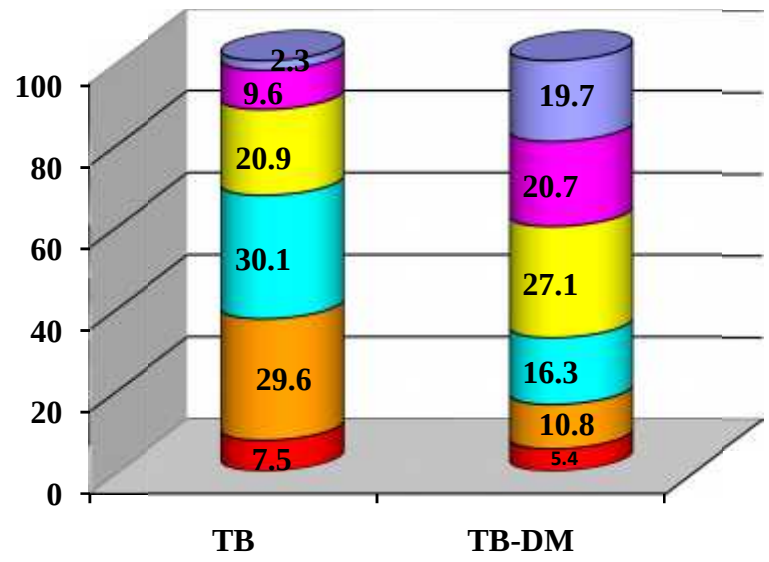
3. Comparison of socio demographic and clinical profile of patients of TB with co- existent DM and TB

The participants in the present study were divided into two groups- TB group and TB-DM group; based on their diabetic status. The socio demographic and clinical profiles of the two groups were compared.

Table 5. Comparison of TB vs TB- DM group according to age (n= 437)

Age	TB	TB-DM	Total
≤20	26 (7.5%)	5 (5.4%)	31
21-30	102 (29.6%)	10 (10.8%)	112
31-40	104 (30.1%)	15 (16.3%)	119
41-50	72 (20.9%)	25 (27.1%)	97
51-60	33 (9.6%)	19 (20.7%)	52
61-70	8 (2.3%)	18 (19.7%)	26
Total	345	92	437
X^2_5= 60.581		***P* <0.001***	

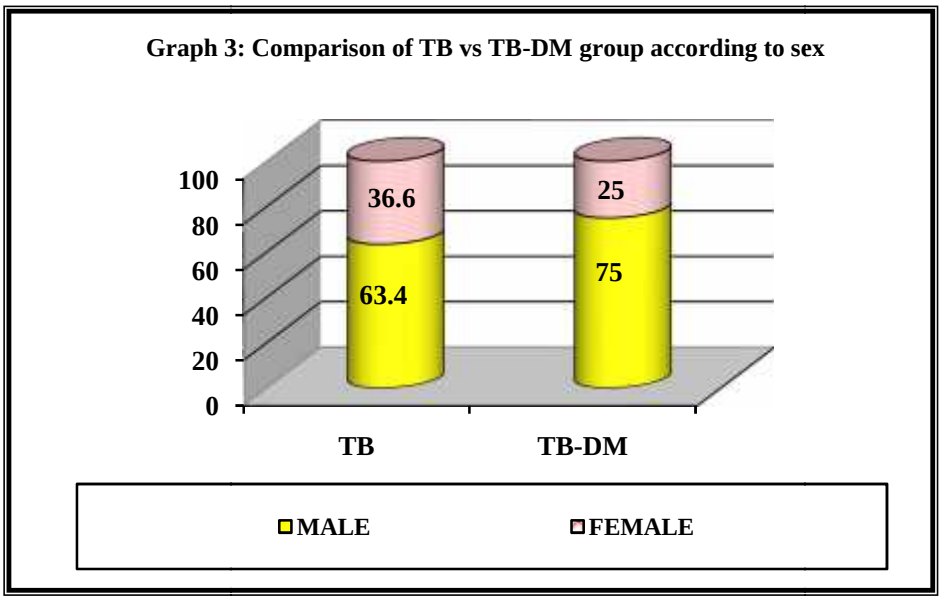
Graph 2: Comparison of TB vs TB-DM group according to age



In the present study; it was observed that among the TB group, the major age group affected was from 21-40 years (59.7%) whereas in the TB-DM group the major age group affected was 41-70 years (67.5%). This difference was found to be statistically significant.

Table 6. Comparison of TB vs TB- DM group according to sex (n= 437)

Sex	TB	TB-DM	Total
Male	219 (63.4%)	69 (75%)	288
Female	126 (36.6%)	23 (25%)	149
Total	345	92	437
X^2_1= 4.291	***P=0.038****		



In the present study, among the TB group 63.4% were males and 36.6% were females whereas in the TB-DM group 75% were males and 25% were females. This difference was statistically significant.

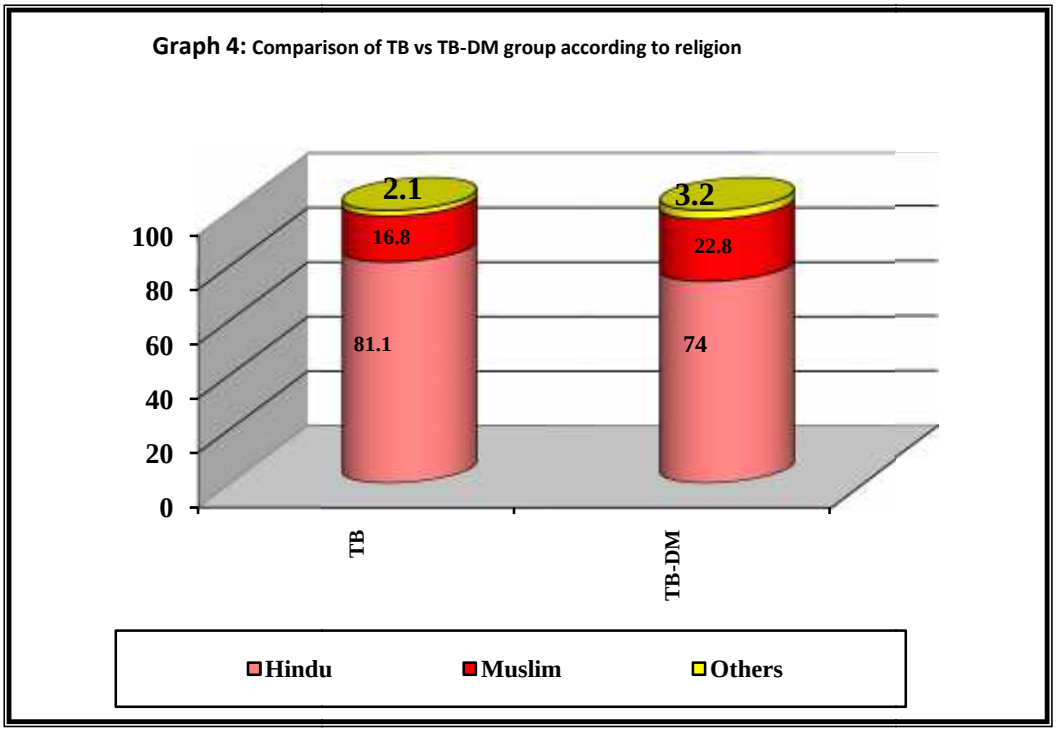
Table 7. Comparison of TB vs TB- DM group according to occupation (n= 437)

Occupation	TB	TB-DM	Total
Professional	0	02 (2.1%)	02
Semi-professional	8 (2.3%)	05 (5.4%)	13
Clerk, Farm owners etc	26 (7.5%)	09 (9.8%)	35
Skilled	48 (13.8%)	12 (13.1%)	60
Semiskilled	82 (23.7%)	19 (20.7%)	101
Unskilled	64 (18.8%)	25 (27.2%)	89
Unemployed	16 (4.6%)	02 (2.1%)	18
Housewife	101 (29.3%)	18 (19.6%)	119
Total	345	92	437
$X^2_7 = 12.961$ ***P=0.044****			

In both TB group as well as TB-DM group the number of participants engaged in skilled (13.8% Vs 13.1%) or semi-skilled (23.7% vs 20.7%) occupation was almost equal. The number of unemployed participants was slightly higher in TB group (4.6%) as compared to TB-DM group (2.1%). More participants were housewives in TB group (29.3%) than TB-DM group (19.6%). The participants who were professionals or semi professionals were 7.5% in TB-DM group as compared to 2.3% in TB group. These differences in observation were found to be statistically significant

Table 8. Comparison of TB vs TB- DM group according to religion (n= 437)

Religion	TB	TB-DM	Total
Hindu	280 (81.1%)	68 (74%)	348
Muslim	58 (16.8%)	21 (22.8%)	79
Others	7 (2.1%)	3 (3.2%)	10
Total	345	92	437
X^2_2= 2.414 **P =0.299**			

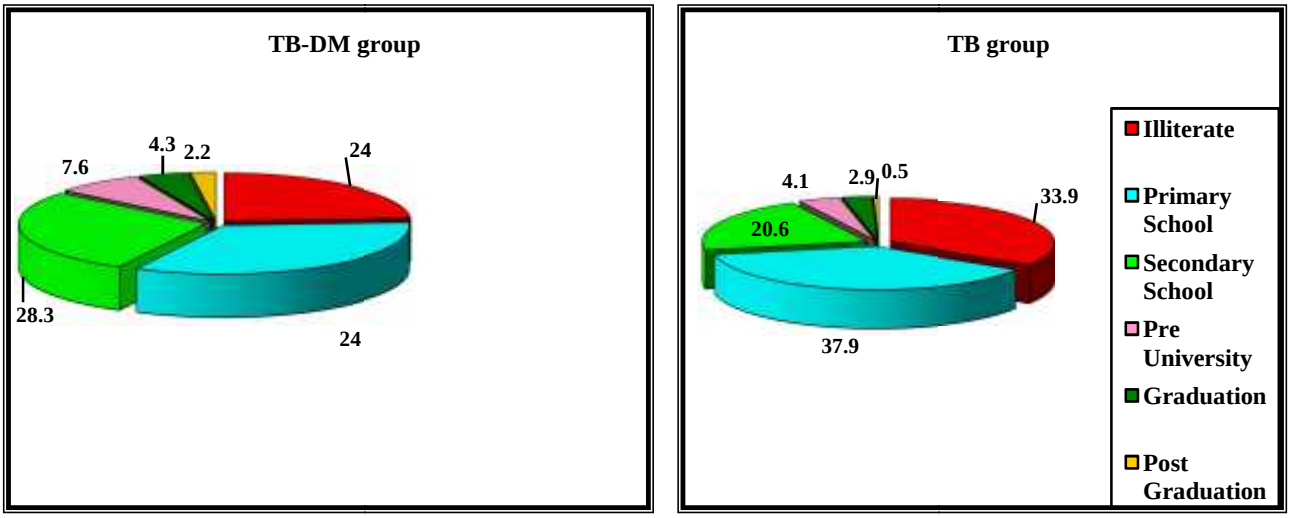


In both groups majority of the participants were Hindus- 81.1% in TB group and 74% in TB-DM group. The proportion of participants belonging to Muslim and other religions were slightly higher in TB-DM group (26%) than TB group (19%). However this difference was statistically not significant.

Table 9. Comparison of TB vs TB- DM group according to educational status (n= 437)

Educational status	TB	TB-DM	Total
Illiterate	117 (33.9%)	22 (24%)	139
Primary school	131 (37.9%)	31 (33.6%)	162
Secondary school	71 (20.6%)	26 (28.3%)	97
Pre University	14 (4.1%)	7 (7.6%)	21
Graduation	10 (2.9%)	4 (4.3%)	14
Post-Graduation	2 (0.5%)	2 (2.2%)	4
Total	345	92	437
X^2_4= 8.111 *P* =**0.088**			

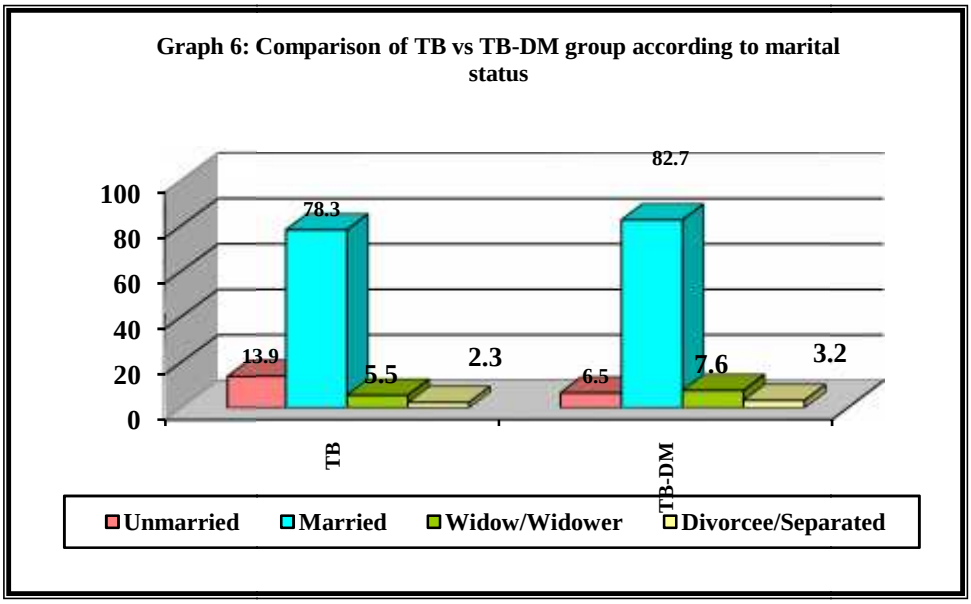
Graph: 5 Comparison of TB vs TB-DM group according to educational status



Majority of the participants have done either primary or secondary schooling in either group- 58.5% in TB group and 61.9% in TB-DM group. 24% of the participants in TB-DM group are illiterate against 33.9% in TB group of participants. However this difference was statistically not significant.

Table 10. Comparison of TB vs TB- DM group according to marital status (n= 437)

Marital status	TB	TB-DM	Total
Unmarried	48 (13.9%)	06 (6.5%)	54
Married	270 (78.3%)	76 (82.7%)	346
Widow/Widower	19 (5.5%)	07 (7.6%)	26
Divorcee /Separated	08 (2.3%)	03 (3.2%)	11
Total	345	92	437
X^2_3= 4.180 **P =0.243**			

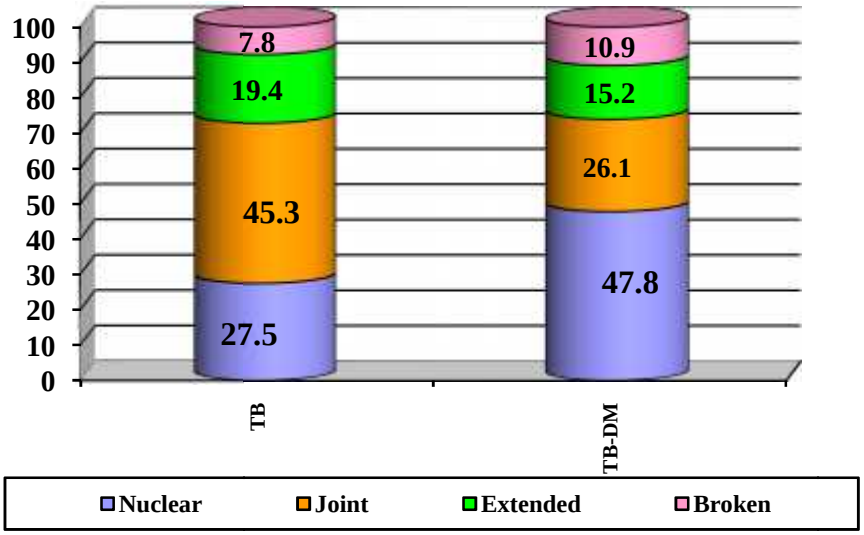


Majority of the participants in the TB group (78.3%) and TB- DM group (82.7%) were married. 13.9% of participants in TB group were unmarried as compared to 6.5% of TB-DM group. This difference was statistically not significant.

Table 11. Comparison of TB vs TB- DM group according to type of family (n= 437)

Type of family	TB	TB-DM	Total
Nuclear	95 (27.5%)	44 (47.8%)	139
Joint	156 (45.3%)	24 (26.1%)	180
Extended	67 (19.4%)	14 (15.2%)	81
Broken	27 (7.8%)	10 (10.9%)	37
Total	345	92	437
X^2_3= 17.341 *P* =0.001*			

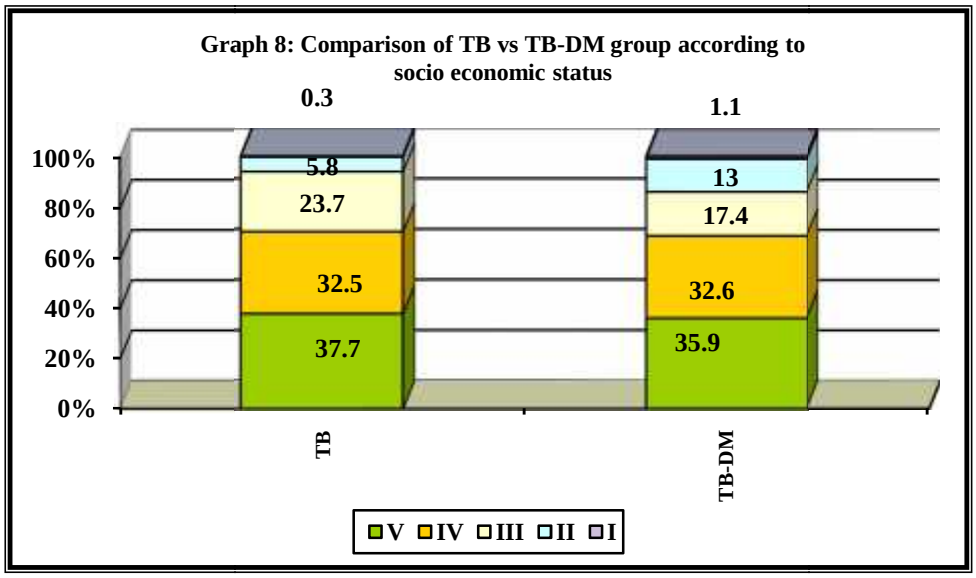
Graph 7: Comparison of TB vs TB-DM group according to type of family



Maximum number of participants in the TB group belonged to joint family (45.3%) followed by nuclear family (27.5%); whereas in TB-DM group maximum number of participants stayed in nuclear family (47.8%) followed by joint family (26.1%). This difference in family type was statistically significant.

Table 12.Comparison of TB vs TB- DM group according to Socio economic Status (n= 437)

Socioeconomic status	TB	TB-DM	Total
I	01 (0.3%)	01 (1.1%)	2
II	20 (5.8%)	12 (13%)	32
III	82 (23.7%)	16 (17.4%)	98
IV	112 (32.5%)	30 (32.6%)	142
V	130 (37.7%)	33 (35.9%)	163
Total	345	92	437
X^2_3= 7.421 ***P* =0.060**			



Majority of the study participants in both TB group (93.5%) as well as TB-DM group (85.9%) belonged to SES class III, IV or V. However in TB-DM group around 14.1% of the participants belonged to SES class II and I as compared to 6.5% in TB group. This difference was statistically not significant.

Table 13. Comparison of TB vs TB- DM group according to ventilation at house (n= 437)

Ventilation	TB	TB-DM	Total
Well ventilated	103 (31.6%)	29 (31.5%)	132
Ill ventilated	242 (68.4%)	63 (68.5%)	305
Total	345	92	437
X^2_1= 0.096 **P =0.757**			

Almost equal proportion of participants lived in ill ventilated house in either group- 68.4% in TB group and 68.5% in TB-DM group.

Table 14. Comparison of TB vs TB- DM group according to overcrowding at residence (n= 437)

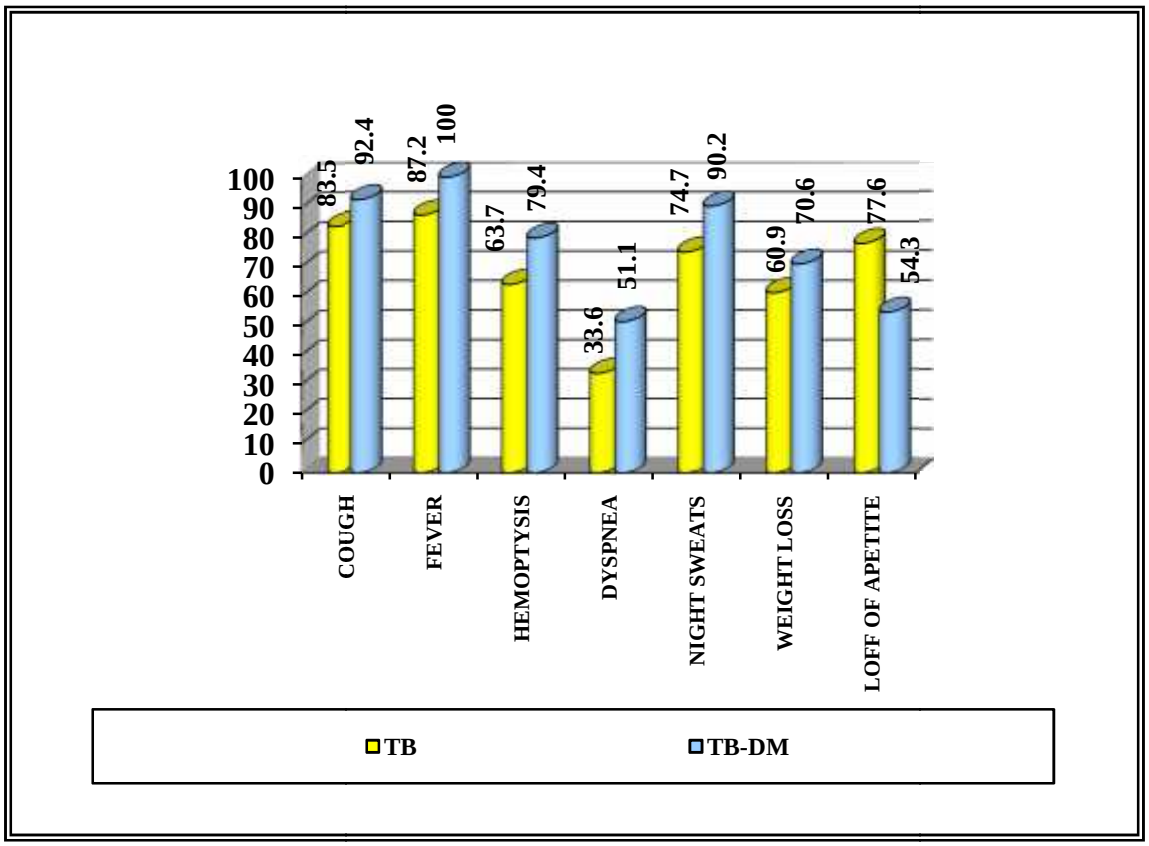
Overcrowding	TB	TB-DM	Total
Absent	136 (39.4%)	40 (43.5%)	176
Present	209 (60.6%)	52 (56.5%)	261
Total	345 (78.9%)	92 (21.1%)	437
X^2_1= 0.497 **P =0.481**			

Overcrowding at residence was found to be slightly more in TB group (60.6%) as compared to TB-DM group (56.5%), but this difference was statistically not significant.

Table 15. Comparison of TB vs TB- DM group according to the presence of Symptoms (n= 437)

Presence of symptoms		TB	TB-DM	
Cough	**Present**	**288 (83.5%)**	**85 (92.4%)**	X^2_1 **= 4.616** *P* **= 0.032***
	Absent	**57 (16.5%)**	**7 (7.6%)**	
Fever	**Present**	**301 (87.2%)**	**92 (100%)**	X^2_1**= 13.047** *P* **< 0.001***
	Absent	**44 (12.8%)**	**0**	
Hemoptysis	**Present**	**220 (63.7%)**	**73 (79.4%)**	X^2_1**=7.980** *P* **= 0.005***
	Absent	**125 (36.3%)**	**19 (20.6%)**	
Dyspnea	**Present**	**116 (33.6%)**	**47 (51.1%)**	X^2_1**= 9.472** *P* **= 0.002***
	Absent	**229 (66.4%)**	**45 (48.9%)**	
Night sweats	**Present**	**258 (74.7%)**	**83 (90.2%)**	X^2_1**=10.094** *P* **= 0.001***
	Absent	**87 (25.3%)**	**09 (9.8%)**	
Weight loss	**Present**	**210 (60.9%)**	**65 (70.6%)**	X^2_1**=2.980** *P* **= 0.084**
	Absent	**135 (39.1%)**	**27 (29.4%)**	
Loss of appetite	**Present**	**268 (77.6%)**	**50 (54.3%)**	X^2_1**= 23.672** *P* **< 0.001***
	Absent	**77 (22.4%)**	**42 (45.7%)**	

Graph: 9 Comparison of TB vs TB-DM group according to presence of symptoms

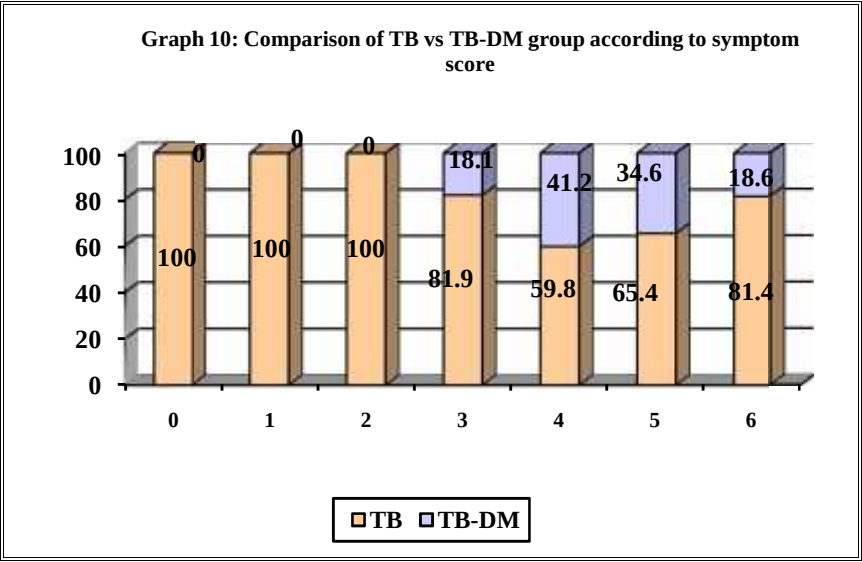


Participants were asked for the cardinal symptoms of TB such as cough, fever, hemoptysis, dyspnea, night sweats, weight loss and loss of appetite. The proportion of patients with presence of each of these symptoms in TB vs TB-DM were; cough- 83.5% vs 92.4%, fever- 87.2% vs 100%, hemoptysis- 63.7% vs 79.4%, dyspnea- 33.6% vs 51.1%, night sweats- 74.7% vs 90.2%, weight loss- 60.9% vs 70.65, loss of appetite- 77.6% vs 54.3%. Except for loss of appetite the patients in TB-DM group were more symptomatic than patients in TB group at presentation. This was statistically found to be significant.

Table 16. Comparison of TB vs TB- DM group according to symptom score (n= 437)

A symptom score was calculated on the basis of presence of cough, hemoptysis, dyspnea, fever, night sweats, weight loss and loss of appetite (one point for each item). Patients with a symptom score ≥ 4 were classified as highly symptomatic

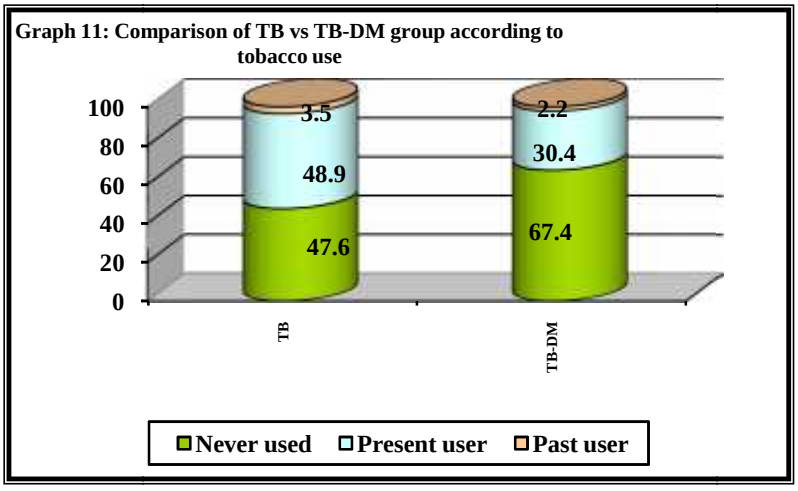
Symptom score	TB	TB-DM	Total
0	44 (12.8%)	0	44
1	4 (1.2%)	0	4
2	45 (13%)	0	45
3	59 (17.1%)	13 (14.1%)	72
4	10 (2.9%)	7 (7.7%)	17
5	100 (28.9%)	53 (57.6%)	153
6	83 (24.1%)	19 (20.6%)	102
Total	345	92	437
X^2_5= 46.688	***P* <0.002***		



In the present study it was observed that among the 94 patients who presented with either no symptoms or less than two symptoms none belonged to the TB-DM group. Patients with TB-DM group had more symptoms (≥ 3) at presentation as compared to TB group. This was found to be statistically significant.

Table 17. Comparison of TB vs TB- DM group according to tobacco use(n= 437)

Tobacco use	TB	TB-DM	Total
Never used	164 (47.6%)	62 (67.4%)	226
Present user	169 (48.9%)	28 (30.4%)	197
Past user	12 (3.5%)	02 (2.2%)	14
Total	345	92	437
X^2_2= 11.467 ***P* =0.003***			

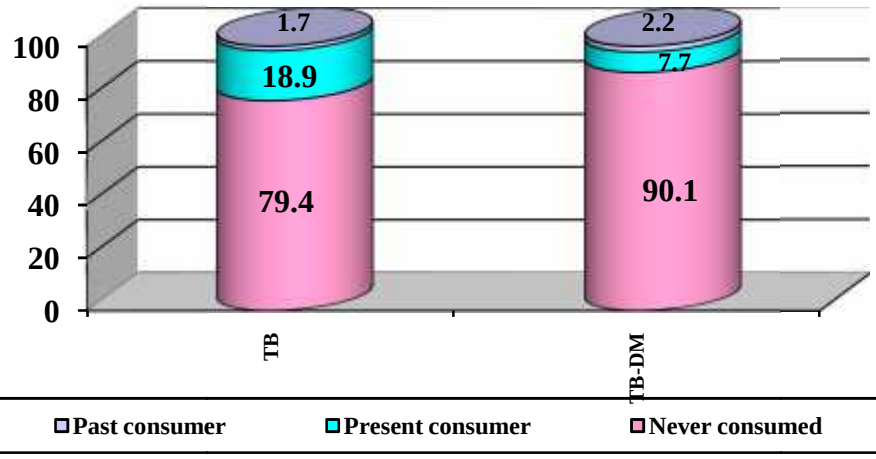


From the present study it was observed that the participants who used tobacco in any form; ie, smoking or smokeless form, were comparatively higher in TB group (48.9%) than TB-DM group (30.4%). This difference was found to be statistically significant.

Table 18. Comparison of TB vs TB- DM group according to alcohol Consumption (n= 437)

Alcohol consumption	TB	TB-DM	Total
Never consumed	274 (79.4%)	83 (90.1%)	357
Present consumer	65 (18.9%)	7 (7.7%)	72
Past consumer	6 (1.7%)	2 (2.2%)	8
Total	345	92	437
X^2_2= 6.673 ***P* =0.036***			

Graph 12: Comparison of TB vs TB-DM group according to alcohol consumption



From the present study it was observed that the participants who currently consumed alcohol were comparatively higher in TB group (18.9%) than TB-DM group (7.7%). This difference was found to be statistically significant.

Table 19. Comparison of TB vs TB- DM group according to type of diet (n= 437)

Type of diet	TB	TB-DM	Total
Vegetarian	233 (67.5%)	46 (50%)	281
Ovo vegetarian	23 (6.7%)	8(8.7%)	31
Non vegetarian	89 (25.8%)	38 (41.3%)	129
Total	345	92	437
X^2_1= 5.778 ***P* =0.016***			

In the present study it was seen that more number of participants in TB-DM group (41.3%) consumed non-vegetarian diet as compared to TB group (25.8%) and this difference was found to be statistically significant.

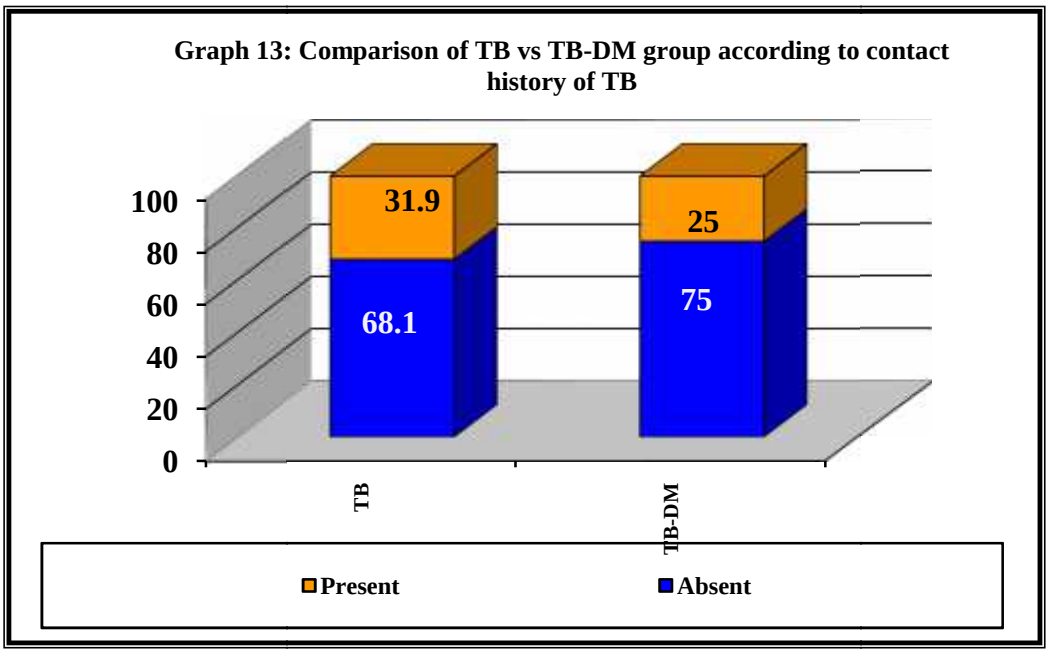
Table 20. Comparison of TB vs TB- DM group according to physical activity (n= 437)

Physical activity	TB	TB-DM	Total
Sedentary	148 (42.9%)	52 (56.5%)	200
Moderate	154 (44.6%)	32 (34.8%)	186
Heavy	43 (12.5%)	8 (8.7%)	51
Total	345	92	437
X^2_2= 6.673 ***P* =0.036***			

Majority of the participants in the TB-DM group (56.5%) had sedentary type of physical activity as compared to 42.9% participants in the TB group. This difference was statistically significant.

Table 21: Comparison of TB vs TB- DM group according to contact history of TB (n= 437)

Contact history	TB	TB-DM	Total
Absent	235 (68.1%)	69 (75%)	304
Present	110 (31.9%)	23 (25%)	133
Total	345	92	437
X^2_1= 1.626 *P* =**0.202**			

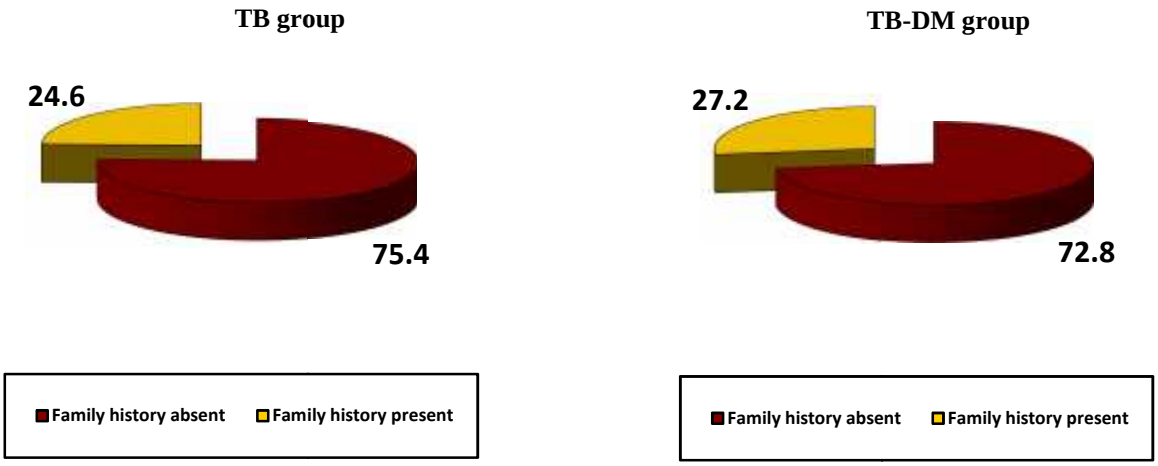


In this study it was observed that among TB group 68.1% of participants had a contact history of TB as compared to 75% in TB-DM group. However this was statistically not significant.

Table 22. Comparison of TB vs TB- DM group according to family history of DM (n= 437)

Family history of DM	TB	TB-DM	Total
Absent	260 (75.4%)	67 (72.8%)	327
Present	85 (24.6%)	25 (27.2%)	110
Total	345	92	437
X^2_1= 0.248 **P =0.618**			

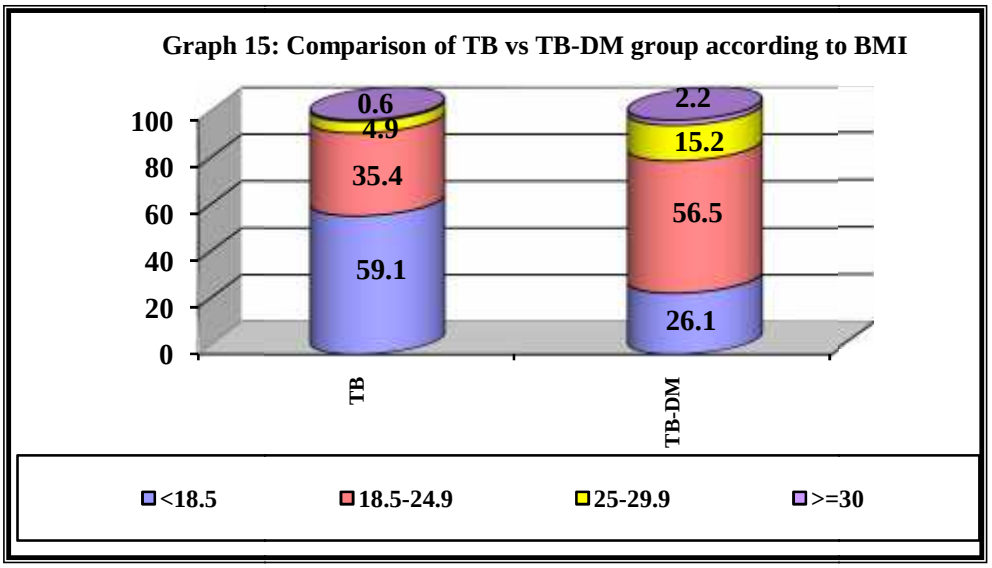
Graph 14: Comparison of TB Vs TB-DM group based on family history of DM



In this study it was observed that among TB group 75.4% of participants had a family history of TB as compared to 72.8 % in TB-DM group. However this was statistically not significant.

Table 23. Comparison of TB vs TB- DM group according to BMI (n= 437)

BMI	TB	TB-DM	Total
< 18.5	204 (59.1%)	24 (26.1%)	228
18.5-24.9	122 (35.4%)	52 (56.5%)	174
25-29.9	17 (4.9%)	14 (15.2%)	31
≥30	02 (0.6%)	02 (2.2%)	4
Total	345	92	437
X^2_1= 36.175 ***P* <0.001***			



Only 26.1% of the participants in TB-DM group were under nourished as compared to 59.1% in TB group. Obese individuals were more in TB-DM group (2.2%) than TB group (0.6%). These differences were statistically significant.

Table 24. Comparison of male participants of TB vs TB- DM group according to waist circumference (n= 288)

Waist circumference	TB	TB-DM	Total
>90 cms	40 (18.3%)	24 (34.8%)	64
< 90 cms	179 (81.7%)	32 (65.2%)	224
Total	219	69	288
X^2_1= 36.175 ***P* <0.001***			

Among the male participants in the TB-DM group 34.8% of were having waist circumference more than 90 cms as compared to 18.3% in TB group. This difference was statistically significant.

Table 25. Comparison of female participants of TB vs TB- DM group according to waist circumference (n=149)

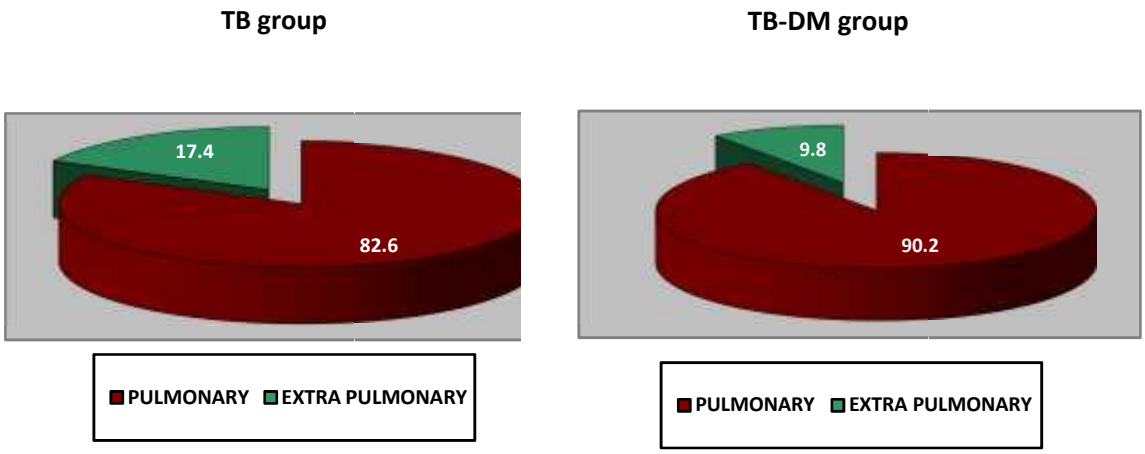
Waist circumference	TB	TB-DM	Total
>80cm	19 (15.1%)	12 (52.2%)	31
< 80cm	107 (84.9%)	11 (47.8%)	118
Total	126	23	149
X^2_2= 11.467 ***P* =0.003***			

Among the female participants in the TB-DM group 52.2% of were having waist circumference more than 80 cms as compared to 15.1% in TB group. This difference was statistically significant.

Table 26. Comparison of TB vs TB- DM group according to type of TB (n= 437)

Type of TB	TB	TB-DM	Total
Pulmonary	285 (82.6%)	83 (90.2%)	368
Extra -Pulmonary	60 (17.4%)	9 (9.8%)	69
Total	345	92	437
X^2_1= 3.162 ***P* =0.025***			

Graph: 16 Comparison of TB vs TB-DM according to type of TB

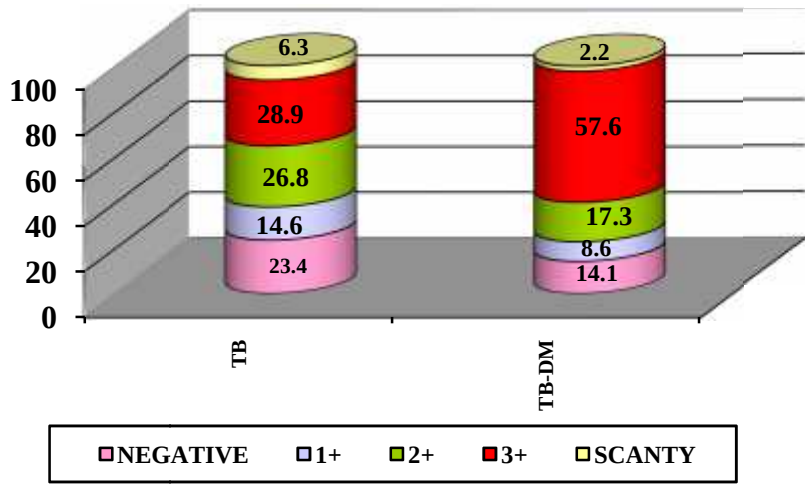


90.2% patients in TB-DM group presented with pulmonary form of TB as against 82.6% in TB group and this difference was statistically significant.

Table 27. Comparison of TB vs TB- DM group according to sputum result (n= 437)

Sputum result	TB	TB-DM	Total
NEGATIVE	82 (23.4%)	13 (14.1%)	95
1+	50 (14.6%)	8 (8.6%)	58
2+	92 (26.8%)	16 (17.3%)	108
3+	100 (28.9%)	53 (57.6%)	153
SCANTY	21 (6.3%)	2 (2.2%)	23
Total	345	92	437
X^2_1= 26.580 P < **0.001***			

Graph 17: Comparison of TB vs TB-DM group according to sputum result

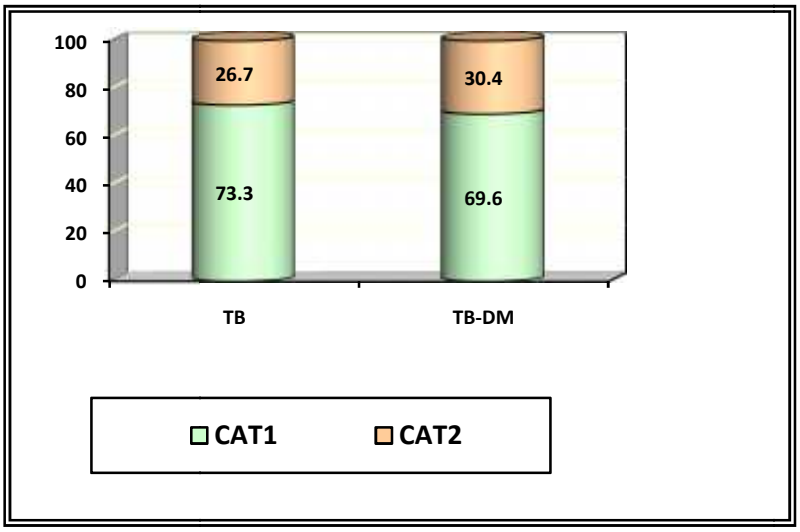


The sputum result showed +++ bacterial load in 57.6% of patients in TB-DM group as compared to only 26.8% in TB group and this difference was found to be statistically significant

Table 28. Comparison of TB vs TB- DM group according to treatment category (n= 437)

Treatment category	TB	TB-DM	Total
CAT 1	253 (73.3%)	64 (69.6%)	317
CAT 2	92 (26.7%)	28 (30.4%)	120
Total	345	92	437
X^2_1= 0.518 ***P* =0.477**			

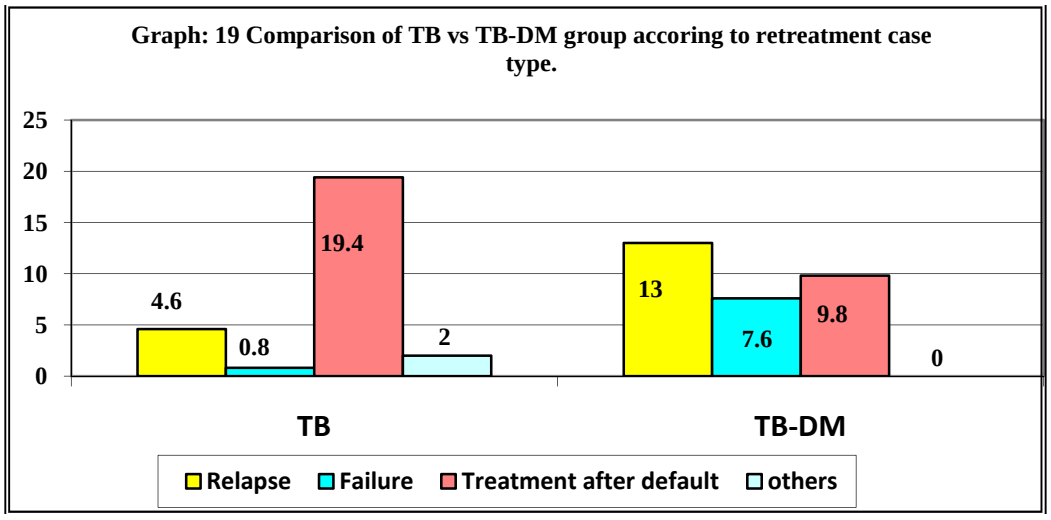
Graph 18: Comparison of TB vs TB-DM group according to category of TB



73.7% of the participants in TB group and 69.6% of the participants in TB-DM group were put on category 1 treatment. 26.7% of participants in TB group and 30.4% of the participants in TB-DM group were put in category II treatment. This difference was statistically not significant.

Table 29. Comparison of TB vs TB- DM group according to retreatment case type (n = 120)

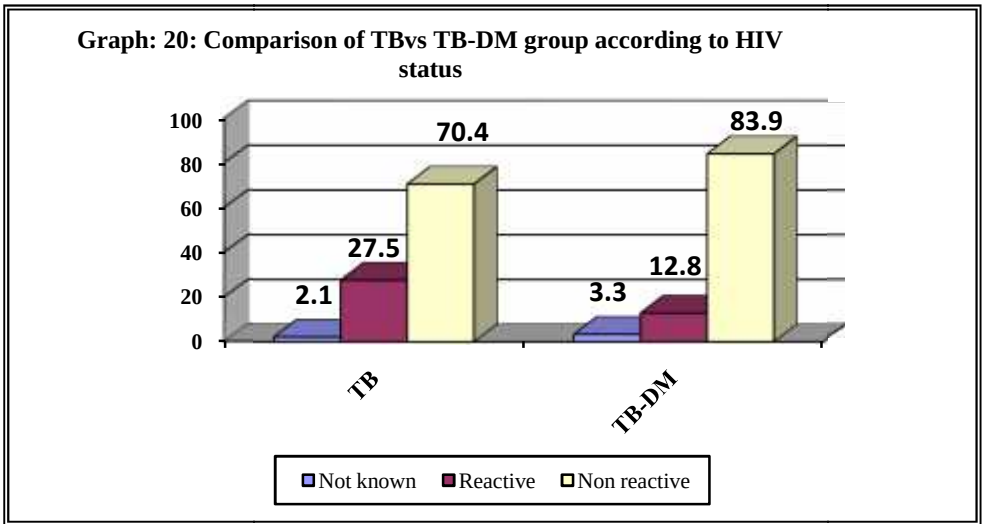
Retreatment case type	TB	TB-DM	Total
Relapse	16 (4.6%)	12 (13%)	28
Failure	03 (0.8%)	07 (7.6%)	10
After Default	66 (19.4%)	9 (9.8%)	76
Others	07 (2%)	0	7
Total	92	28	120
X^2_4= 28.292 $P < 0.001$*			



Relapse and failure cases were more in TB-DM group as compared to TB group; ie, 13% and 7.6% vs 4.6% and 0.8% respectively. Whereas treatment after default cases were more in TB group (19.4%) as compared to TB-DM group (9.8%). These differences were found to be statistically significant.

Table 30. Comparison of TB vs TB- DM group according to HIV status

HIV Status	TB	TB-DM	Total
Not Known	7 (2.1%)	3 (3.3%)	10
Reactive	95 (27.5%)	11 (12.8%)	116
Non reactive	243 (70.4%)	78 (83.9%)	311
Total	345	92	437
X^2_2= 1.212 **P = 0.545**			



27.5% participants in the TB group and 12.8% in the TB-DM group were co-infected with HIV.

DISCUSSION

This cross sectional study was conducted in three Primary Health Centres (PHC) - Handignur, Vantamuri, Kinaye and three Urban Health Centres (UHC) - Ram Nagar, Asok Nagar, Rukmini Nagar which are the field practice areas of Department of Community Medicine, Jawaharlal Nehru Medical College, Belgaum an in Revised National Tuberculosis Control Programme (RNTCP) unit, Government District Hospital Belgaum. The study was aimed at finding the prevalence of DM among TB patients registered under RNTCP and to compare the socio-demographic and clinical profile of patients with TB-DM with that of TB alone. A total of 437 TB patients were included from all the study areas from January to December 2012.

Socio demographic characteristics of the study participants (Table 1)

In the present study 75% of the patients were in the age group 21-50 years. There were 288 (66%) males and 149 (34%) females with a ratio of 1.9:1. These findings are comparable with a study conducted in Gujarat where 68% of the study participants were males and 32% females with mean age of 34.59 years.[81]Another study conducted in Delhi in 2000 found that 67.6 % of the participants were males and 32.4 % females and the majority (58.8%) of them was in the age group 21-40 years.[82]

In this study it was observed that 80% of the participants were Hindus. A study conducted in Jodhpur in 2004 showed that 70.7% were Hindus and 29.3% belonged to other religion.[83] But in a study conducted in Calcutta in 2001

Muslims outnumbered Hindus (79.7% vs 28.3%) and other religions were absent.[84]

In our study majority of the participants were engaged in skilled, semiskilled or unskilled work. 27.2% were housewives and 4.2% were unemployed. In a study done in TRC, Chennai from 1994-2004 showed that 62% of the patients were employed and 31% were unemployed.[85]Another study done in Baleshwar and Jodhpur in 2004 showed that 55.5% of the participants were labourers, 14.5% were in service, 10.6% were housewives, 3.4% were unemployed and remaining 15.6% self employed.[83]

In the present study majority of the participants were either illiterate (31.8%) or educated up to primary school (37.1%). Only 4% were educated up to graduation or more. This finding was comparable with a cross sectional study done in Gujarat in 2008-2009 which showed that 29% of the participants were illiterate, 46% were primary educated and 6% were graduates.[81] Another study conducted in rural Wardha in 2007 also showed that 40% of the participants studied upto primary level and 5.7% were illiterate.[86]

In our study, 31.8% of the participants belonged to nuclear family, 41% joint families, 18.5% extended families and 8.5% in broken families. 79.2% were married, 12.4% were unmarried, 6% were widows/widowers and 2.5% divorced. Similar results were seen in a study done in Wardha in 2007 wherein 58.5% belonged to nuclear family and 41.5% belonged to joint families. The marital status showed that 77.4% were currently married, 17% unmarried, 3.8% widows/widower and 1.9% divorcees.[86]

In the present study 37.2% of the participants belonged to SES Class V followed by Class IV (32.5%) and Class III (22.4%). Only 8% of the participants belonged to SES class I & II. A study done in Calcutta in 2001 showed that 49.2% belonged to SES Class IV, 25% Class III, 13.3% in Class V and 12.5 % in Class I and II.[84]

Prevalence of DM among TB patients (Table 2, 3, 4)

In the present study 65 patients were known cases of DM whereas 27 patients were newly diagnosed as diabetic by OGTT. Thus out of the 437 study subjects, 92 patients were found to be diabetic giving an overall prevalence of 21.1% (14.9% known cases and 6.2% newly diagnosed).

Various national and international studies have shown a wide range in the prevalence of DM among TB patients viz: Mendez et al [48] - 25.2%, Wang et al [46] - 16.9%, Tatar et al [51] - 7.3%, Qayyum et al [45] - 7.5%, Alisjahbana B et al [43] - 13.2%, Dooley et al [56] -14%, Walker et al[49] - 16.9%, Restrepo et al [47] – 39%, Faurholt et al [53] - 16.7%, Kibirige et al [52] - 8.5%, Li et al [55] -12.4%, Zargar et al [63] - 20.1%, Stevenson et al [60] -18.4%, Balakrishnan et al [64] - 44%, Viswanathan et al [65] - 25.3%, Tuberculosis Association of India (TAI) [62] - 9.2%.

A recent nationwide study conducted by the Tuberculosis-Diabetes Study Group in 2012 to assess the feasibility of screening TB patients for DM, observed an overall prevalence of 13%; out of which 8% were known cases of DM and 5% newly diagnosed. They also observed a region wise difference with 20% prevalence in South India as compared to 10% in North India.[66] Our findings were similar to this study.

Comparison of socio demographic and clinical profile (TB Vs TB-DM)

The participants in the present study were divided into two groups- TB group and TB-DM group; based on their diabetic status. The socio demographic and clinical profiles of the two groups were compared.

Comparison of the study participants according to age (Table 5)

In the present study; significant difference was observed between TB group and TB-DM group with respect to age. Among the TB group, the major age group affected was from 21-40 years (59.7%) whereas in the TB-DM group the major age group affected was 41-70 years (67.5%). This observation was similar to that of a study done in Kerala in 2011 where majority (74%) of the participants in the TB-DM group were above 45 years whereas in the TB group 63% of the patients were between 15 and 44 years.[64] Similar findings were observed in a study done in Saudi Arabia where the mean age group in the TB-DM group was 48.2 years as compared to 32.3 years in the TB group.[87] Another study done in Indonesia showed that median age of patients with TB-DM was 45 years whereas that with TB alone was 27 years. [57]

TB usually affects individuals in the productive age group ie; 20-40 years whereas DM is more common among older individuals. Hence a patient presenting with symptoms of TB or diagnosed as TB at an older age must be seen with a high degree of suspicion of having DM and promptly screened for it.

Comparison of the study participants according to sex (Table 6)

In the present study, among the TB group 63.4% were males and 36.6% were females whereas in the TB-DM group 75% were males and 25% were

females giving a male: female ratio of 1.73: 1 in TB group and 3: 1 in TB-DM group. This significant difference was also observed in a study done in Saudi Arabia, where the male: female ratio among TB-DM patients was 3.1:1 as compared to 1.53:1 among TB patients. [87] But a study done in Indonesia showed a much lesser difference in the male: female ratio between the two groups; ie, 1.24: 1 in TB-DM group Vs 1.1: 1 in TB group. [57]

Comparison of the study participants according to occupation (Table 7)

In the present study it was observed that the number of unemployed participants was slightly higher in TB group (4.6%) as compared to TB-DM group (2.1%). More participants were housewives in TB group (29.3%) than TB-DM group (19.6%). The participants who were professionals or semi professionals were 7.5% in TB-DM group as compared to 2.3% in TB group. On analysis these differences in observation was significant. In a study done in Uganda, it was observed that 22.7% of the participants in TB group were unemployed as against 27.3% in TB-DM group.[52]

Professional and semi professionals are at higher risk of getting DM as they are in sedentary occupation.

Comparison of the study participants according to Religion (Table 8)

In the present study it was observed that in both groups majority of the participants were Hindus. The proportion of participants belonging to Muslim and other religions were slightly higher in TB-DM group (26%) than TB group (19%) but this was not significant. In a study done in Northeastern Ethiopia in 2012 observed that Muslims had a higher proportion of TB-DM patients (9.5%) as compared to Christians and other religions (2.3 %).[54]

Comparison of the study participants according to educational status (Table 9)

In the present study, it was observed that 37.9% of the participants in TB group and 33.6% in TB-DM group had attended primary school. 24% of participants in TB-DM group were illiterate against 33.9% in TB group. Our observations were similar to a study done in Ethiopia where more proportion of participants were found to be suffering from TB-DM co-morbidity among the graduates (26.3%) and higher secondary educated (21%) as compared to illiterates (15.2%) and those educated up to primary level (14.8%).[54] Another study done in Brazil also showed similar findings. 17.2% of the illiterates and 18.2% of the primary school educated were in the TB- DM group whereas among the higher educated 28.3% belonged to TB-DM group.[89]

Comparison of the study participants according to Marital Status (Table 10)

In our study it was observed that more proportion of participants among the widow/widowers/divorcees (27.1%) belonged to the TB-DM group as compared to married (22%) and unmarried (11.1%). Our findings were similar to a study done in Ethiopia were they found that 16.3% and 12.4% among the married and unmarried respectively had TB- DM whereas a slightly higher proportion of divorcees/ widowers(18%) were affected with TB and DM. [54]

Comparison of the study participants according to type of family (Table 11)

In this study it was seen that 31.7% of the participants who lived in nuclear family and 27% who lived in broken family belonged to TB-DM group as compared to 31 % who lived in joint or extended family. This difference in family type between the two groups was found to be significant.

Comparison of the study participants according to Socio economic Status (SES) (Table 12)

In the present study it was noted that 50% of the subjects in SES class I and 37% in SES class II had suffered from both TB and DM. But in other socioeconomic classes the proportion of subjects with TB and DM was less i.e.; 16.3% in SES class III, 21.1% in class IV and 20.2% in class V. A study done in Kerala showed that more participants in TB-DM group belonged to SES class 1 and II (30%) as compared to TB group (21%). However similar to our study, this difference was not significant.

Comparison of the study participants according to ventilation at house and overcrowding (Table 13 & 14)

Among the study participants who live in well ventilated houses 78% belonged to the TB group whereas among those who lived in poorly ventilated houses 80% belonged to the TB group. Among the study participants who lived in houses without overcrowding 77.3% belonged to the TB group whereas those who lived in houses with overcrowding 80.1% belonged to the TB group. The difference observed between the two groups was not significant. A similar cross sectional study done in Indonesia found that 56.2% of the TB patients resided in ill ventilated and overcrowded houses as against 58.4% of TB-DM patients.[43]. Poor housing conditions are well known risk factors for TB. Our study also observed the same.

Comparison of study participants according to the presence of symptoms (Table 15)

In this study seven cardinal symptoms of TB were noted ie; cough, fever, night sweats, hemoptysis, dyspnea, weight loss and loss of appetite. There was significant difference between the two groups with respect to the proportion of patients who presented with these symptoms. The patients affected with both TB and DM was more symptomatic than TB patients. The proportion of patients in TB vs TB-DM group with each of these symptoms are; cough-83.5% vs 92.3%, hemoptysis- 33.6% vs 51.2%, dyspnea- 63.1% vs 79.3%, fever- 87.2% vs 100%, night sweats- 74.85 vs 90.2%, weight loss- 60.9% vs 70.6%, loss of appetite- 77.6% vs 54.3%. Our findings were comparable with a study done in Indonesia where the observation in the TB vs TB-DM group were; cough- 97.8% vs 98.9%, hemoptysis- 40.7% vs 42.6%, dyspnea- 63.7% vs 69.1%, fever- 73.9% vs 80.9%, Night sweats- 70.2% vs 79.8%, weight loss- 80.4% vs 96.8%, loss of appetite- 64.9% vs 59.2%.

Comparison of the study participants according to symptom score (Table 16)

A symptom score was calculated on the basis of presence of cough, hemoptysis, dyspnea, fever, night sweats, weight loss and loss of appetite (one point for each item). Patients with a symptom score ≥ 4 were classified as highly symptomatic.[57] We observed that 85% of the patients belonging to the TB-DM group were highly symptomatic as compared to only 56% of the patients in TB group. Our finding was similar to the Indonesian study which observed 68.3% of TB-DM patients as highly symptomatic as against 48.5% in TB alone.[57]

Comparison of the study participants according to tobacco and alcohol consumption (Table 17 & 18)

In the present study both tobacco consumption and alcohol consumption was found to be significantly more in TB-DM group. It was found that among the TB- DM group 32% were smokers whereas in the TB group 52% were smokers. Similarly 10% of participants in the TB-DM group were alcoholic as compared to 21% in TB group. Our findings were comparable with a study done in turkey were 50% patients in TB group were smokers as compared to 30.8% in TB-DM group and 12.8% of the alcoholics belonged to TB group as against 10.3% who belonged to TB-DM group.[51]Our findings were different from a study done in Uganda where more participants were smokers in the TB-DM group (26.5%) as compared to TB group (13.6%).[52] Another study done in Malaysia showed almost equal prevalence of smokers in both TB-DM group as well as TB group (71% and 70% respectively). Alcoholics were also in equal proportion in both the groups ie; 1% each in this study.[88]

Comparison of study participants according to type of diet (Table 19)

In the present study TB-DM was found in 27.2 % of the participants who took mixed diet and in 17.5% of the participants who were vegetarians. Though the observation did not show any statistical difference, it was expected as non vegetarian diet which is high in saturated fats is a known risk factor for DM.

Comparison of study participants according to physical activity (Table 20)

Statistically significant difference was observed between the two groups with respect to physical activity. 56.5% participants in the TB-DM group had sedentary type of physical activity as compared to 42.9% participants in the TB

group. A study done in Chennai observed that 52% participants in the TB-DM group had sedentary type of physical activity as compared to 22 % in the TB group.[65]

Comparison of study participants according to contact history of TB (Table 21)

In our study, no significant difference was found between the two groups with respect to contact history of TB. Among the TB group 31.9% had contact history of TB as compared to 25% in TB-DM group. In a study done in Indonesia in 2005 it was seen that among the TB group 42.6% had a family history of TB whereas only 29.9% of TB-DM group had a family history of TB.[43]Another study done in Malaysia showed that 19.4% and 19.1% had family history of TB in TB group and TB-DM group respectively. [88]

Comparison of study participants according to family history of DM (Table 22)

In the present study no significant difference was observed between the two groups with respect to family history of DM. 24.6% of the patients in the TB group had a family history of DM and 27.2% of patients in TB-DM group had a family history of DM. This difference was not. This observation was different from a study done in Chennai, where they observed that having a positive family history was significantly more in TB-DM group (29%) than TB group (13%).[65]

Comparison of study participants according to BMI (Table 23)

In this study it was seen that only 26.1% of the participants in TB-DM group were under nourished as compared to 59.1% in TB group. Obese individuals were more in TB-DM group (2.2%) than TB group (0.6%). These differences were found to be very significant. A similar observation was made in a study done in China where 5.4% of patients in TB-DM group were under nourished as compared to 1.8% in TB group.[44] Another study done in Uganda

showed significant difference in the under nourished proportion of people in the two groups-51.9% in TB group and 5.7% in TB-DM group.[52]

Comparison of study participants according to waist circumference (Table 24 & 25)

Among the male participants in the TB-DM group 34.8% of were having waist circumference more than 90 cms as compared to 18.3% in TB group. Among the female participants in the TB-DM group 52.2% of were having waist circumference more than 80 cms as compared to 15.1% in TB group. These differences in waist circumferences between the two groups were found to be statistically significant in either sex. Our observation was comparable with a study done in Chennai were they observed similar significant difference in waist circumference between the two groups with OR- 2.2.[65]

Comparison of the study participants according to type of TB (Table 26)

In this study it was found that 90.2% patients in TB-DM group presented with pulmonary form of TB as against 82.6% in TB group. This difference was statistically significant. Similar observations were made in a study done in Malaysia where pulmonary form of the disease was seen in 79.1% of TB patients and in 90.5% of TB-DM patients.[88] Another study done in Turkey also observed similar trend. They found 82.1% of patients in the TB-DM group affected with the pulmonary form compared to 62.9% of patients in the TB group.[51] A study done in Chennai also observed a greater prevalence of pulmonary form in TB-DM group (87.2%) compared to TB group (75.9%).[65]

Comparison of study participants according to sputum result (Table 27)

In our study we observed that patients in TB-DM group were significantly more sputum positive than patients in TB group. The sputum result showed +++ bacterial load in 57.6% of patients in TB-DM group as compared to only 26.8% in TB group. Our findings were similar to the observation of a study done in

Saudi Arabia where 65.2% of the patients with TB-DM showed numerous bacilli in sputum microscopy as against 54.1% with TB alone.[87] A study done in Indonesia also showed that TB-DM group showed more bacterial load at presentation than TB group. (Sputum mycobacterial load ++ /+++ before treatment- 76% in TB-DM group and 62.4% in TB group).[57] The high bacterial load may be because of the severe immune dysfunction caused by DM which allows the tubercle bacilli to multiply profusely.

Comparison of study participants according to treatment category (Table 28)

In this study it was observed that 73.3% and 69.6% of the patients belonging to TB and TB-DM group respectively were started on Category I treatment. In a study done in Kerala study 84.7% patients in TB group and 81.7% of the patients in TB-DM group were put in Category I treatment.[64]According to RNTCP all new cases of pulmonary or extra pulmonary TB must be started with category I treatment. The difference in observation from the Kerala study may be due to the fact that there is greater number of relapse, failure or default cases in our study area. Relapse, failure and default cases are started with Category II treatment in RNTCP.

Comparison of study participants according to retreatment case type (Table 29)

From this study it was observed that relapse and failure cases were significantly more in TB-DM group as compared to TB group; ie, 13% and 7.6% vs 4.6% and 0.8% respectively. Whereas treatment after default cases were more in TB group (19.4%) as compared to TB-DM group (9.8%). Our observations are comparable to the study done in Chennai where 9 % of the patients in the TB-DM group were relapse cases whereas only 5.2% in TB group was relapse. Failure cases were also comparatively higher in the TB-DM group (7%) than TB group

(4.3%).[65] Since DM is a chronic disease, the possibility of recurrence of TB infection seems high in uncontrolled cases of diabetes. An increase number of failure cases may also be contributed to the poor glycemic control. Some studies have shown that resistance to TB medication and failure cases are high when TB is co affected with DM. [56, 58]

Comparison of the study participants according to HIV status (Table 30)

In our study we observed that HIV co- infectivity was significantly more associated with TB group (27.5%) as compared to TB-DM (12.8%) group. Our findings were similar to the observation made by a study done in South Texas-Mexico border wherein they observed that HIV co-infection was present in 23.2 % of patients with TB-DM and in only 12.7% of patients with TB alone.[50] Another study done in Uganda showed that when 81.5% of TB patients had HIV co-infectivity, the same was present in only 59.1% of TB-DM patients.[52] Considering the fact that both HIV infection and DM are conditions which compromise the immune system, the occurrence of these two diseases together in an individual increases his chance of developing latent TB. Moreover the adverse effects due to medications of these three diseases might increase the chances for default.

CONCLUSION

In the present study the prevalence of DM among TB patients was found to be 21.1% of which one third of the cases were newly diagnosed. Early intervention which can check the progression of TB-DM co-morbidity will go a long way in reducing socio economic burden and thereby improving the quality of life and life expectancy. Both the diseases should be targeted simultaneously with lifestyle modification and pharmacological treatment via a step wise approach.

LIMITATIONS

Some of the limitations of the study were:

1) HbA1c (Glycosylated hemoglobin) could not be done in TB-DM patients to know their previous glycemic status due to financial constraints.

2) Though the newly diagnosed cases of DM were referred promptly to diabetologists, further follow up was not possible.

RECOMMENDATIONS

1) Every diabetic patient should be told about his/her risk of acquiring TB and vice versa. Those affected with the co-morbidity should strictly follow the medications and needs frequent follow up.
2) Physicians or diabetologists must seek relevant history regarding the symptoms of TB from chronic diabetes patients during follow up visits and promptly investigate if needed. Similarly every doctor treating a TB patient must make sure that his patient's glycemic status is known.
3) Community participation and support is essential to tackle this brewing double trouble.
4) Non Governmental Organisations (NGO's) and Pharmacological companies must be actively involved in the programme and help must be sought to provide medications and emergency care and support to those suffering from the co-morbidity.
5) At policy level separate guidelines should be set for the treatment of patients with TB and DM.
6) The role of media is paramount for pinning down this dangerous liaison. Print as well as electronic media can pass on the message of bi directional association of TB and DM to the general public.

SUMMARY

The present cross sectional study was conducted in three Primary Health Centres (PHC) - Handignur, Vantamuri, Kinaye and three Urban Health Centres (UHC) - Ram Nagar, Asok Nagar, Rukmini Nagar and in RNTCP unit, Government District Hospital Belgaum. The study was aimed at finding the prevalence of DM among TB patients registered under RNTCP and to compare the socio-demographic and clinical profile of patients with TB-DM with that of TB alone. A total of 437 TB patients were included from all the study areas from January 2012- December 2012. RNTCP registers maintained at the Primary Health Centres, Urban Health Centres and Government District Hospital, Belgaum was used to identify the patients.

After obtaining the consent, a pretested questionnaire was used to collect information regarding socio demographic details and habitual risk factors viz., smoking, alcohol consumption, other forms of tobacco use; family history of TB and DM, educational and occupational status, and monthly income. Type of TB, HIV status and category of TB treatment were also recorded. The patients were clinically examined by the investigator and anthropometric measurements viz., height, weight, and waist circumference were measured by standard procedure.

Screening for diabetes was done by estimating the Fasting Blood Glucose (FBG) in capillary blood, using glucose-oxidase strips read in a reflectance meter (Accu check glucometer system).Those who showed an FBS value of ≥ 110mg/dl were subjected to Oral Glucose Tolerance Test (OGTT). After an overnight fast of 8-14 hours fasting venous sample was collected. A 75 grams glucose solution

was administered, and venous blood glucose was measured 2 hours later. Diagnosis of diabetes was based on previous history of diabetes or on WHO criteria for the classification of glucose tolerance.

Socio-demographic characteristics

Majority of the patients were in the age group 21-50 years. The male: female ratio was 1.9:1. 80% of the participants were Hindus. Majority of the participants were engaged in skilled, semiskilled or unskilled work. 27.7% were housewives and 4.2% were unemployed. Majority of the participants were either illiterate (31.8%) or educated up to primary school (37.1%). Only 4% were educated up to graduation or more. Most of the participants belonged to nuclear family (31.8%) and joint family (41%). Majority of them were married (79.2%), 12.4% were unmarried, 6% were widows/widowers and 2.5% divorced. 37.2% of the participants belonged to SES Class V followed by Class IV (32.5%) and Class III (22.4%).

Prevalence of DM among TB patients

In the present study 65 patients were known cases of DM whereas 27 patients were newly diagnosed as diabetic by OGTT. Thus out of the 437 study subjects, 92 patients were found to be diabetic giving an overall prevalence of 21.1% (14.9% known cases and 6.2% newly diagnosed).

Comparison of socio demographic and clinical profile between TB group and TB-DM group

In the present study; it was observed that among the TB group, the major age group affected was from 21-40 years (59.7%) whereas in the TB-DM group the major age group affected was 41-70 years (67.5%). Among the TB group 63.4% were males and 36.6% were females whereas in the TB-DM group 75% were males and 25% were females giving a male: female ratio of 1.73: 1 in TB group and 3: 1 in TB-DM group. The number of unemployed participants was slightly higher in TB group (4.6%) as compared to TB-DM group (2.1%). More participants were housewives in TB group (29.3%) than TB-DM group (19.6%). The participants who were professionals or semi professionals were 7.5% in TB-DM group as compared to 2.3% in TB group. In both groups majority of the participants were Hindus. The proportion of participants belonging to Muslim and other religions were slightly higher in TB-DM group (26%) than TB group (19%). Majority of the participants in the TB group (78.3%) and TB- DM group (82.7%) were married. Among the study participants who live in well ventilated houses 78% belonged to the TB group whereas among those who lived in poorly ventilated houses 80% belonged to the TB group. Among the study participants who lived in houses without overcrowding 77.3% belonged to the TB group whereas those who lived in houses with overcrowding 80.1% belonged to the TB group. 37.9% of the participants in TB group and 33.6% in TB-DM group had attended primary school and 24% of participants in TB-DM group were illiterate as against 33.9% in TB group. Most of the participants belonged to nuclear family or joint family in either group. Majority of the study participants in both

TB group (93.5%) as well as TB-DM group (85.9%) belonged to SES class III, IV or V. However in TB-DM group around 14.1% of the participants belonged to SES class II and I as compared to 6.5% in TB group.

A symptom score was calculated on the basis of presence of cough, hemoptysis, dyspnea, fever, night sweats, weight loss and loss of appetite (one point for each item). Patients with a symptom score ≥ 4 were classified as highly symptomatic. It was observed that 85% of the patients belonging to the TB-DM group were highly symptomatic as compared to only 56% of the patients in TB group.

Among the TB- DM group 32% were smokers whereas in the TB group 52% were smokers. Similarly 10% of participants in the TB-DM group were alcoholic as compared to 21% in TB group. Among the TB group 31.9% had contact history of TB as compared to 25% in TB-DM group. 24.6% of the patients in the TB group had a family history of DM and 27.2% of patients in TB-DM group had a family history of DM. It was seen that only 26.1% of the participants in TB-DM group were under nourished as compared to 59.1% in TB group. Obese individuals were more in TB-DM group (2.2%) than TB group (0.6%).

90.2% patients in TB-DM group presented with pulmonary form of TB as against 82.6% in TB group. TB-DM group were more sputum positive than patients in TB group. The sputum result showed 3+ bacterial load in 57.6% of patients in TB-DM group as compared to only 26.8% in TB group. 73.3% and 69.6% of the patients belonging to TB and TB-DM group respectively were started on Category I treatment. It was observed that relapse and failure cases

were more in TB-DM group as compared to TB group; ie, 13% and 7.6% vs 4.6% and 0.8% respectively. Whereas treatment after default cases were more in TB group (19.4%) as compared to TB-DM group (9.8%). HIV co- infectivity was more associated with TB group (27.5%) as compared to TB-DM (12.8%) group.

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ANNEXURE I - ETHICAL CLEARANCE CERTIFICATE

K.L.E.SOCIETY'S
JAWAHARLAL NEHRU MEDICAL COLLEGE,
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Ref: MDC/PG/ገኦኘ **Date: 21/10/2011**

To,

REG. NO.BD0111004
Postgraduate Student,
Department of Community Medicine,
J.N.Medical College,
BELGAUM.

Sub: Institutional Ethical Clearance for the study.

REG. NO.BD0111004

With reference to the above, I wish to inform you that the research project "**PREVALENCE OF DIABETES MELLITUS AMONG TUBERCULOSIS PATIENTS REGISTERED UNDER REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME**", is Ethical and justifiable and has been cleared by the departmental Ethical Committee and College Dissertation and Research Committee.

(Dr. P.V. Patil),
Chairman
College Ethical Dissertation
And Research Committee,
J.N.Medical College, Belgaum.

ANNEXURE III

INFORMED CONSENT

'Prevalence of diabetes mellitus among tuberculosis patients registered under Revised National tuberculosis Control Programme'

INVESTIGATORS:

Introduction (purpose of study):
The present study is conducted among tuberculosis patients registered under RNTCP in the primary health centres – Handiganur, Kinaye & Vantamuri urban health centres- Ram nagar, Asok nagar, Rukmini nagar & Belgaum Institute of Medical Sciences to know the prevalence of diabetes among tuberculosis patients.

Methodology (Explanation of Procedures):
You will be interviewed using a questionnaire and also be examined clinically. Your fasting blood sugar level will be estimated using glucometer and strips by capillary method. Those patients who show an FBS value of ≥ 110mg% will be subjected to Oral glucose tolerance test (OGTT).

Possible benefits:
You will not be eligible for any kind of monetary benefits or free medical services by virtue of your participation in the study. However you will be benefitted by the health education given during the study regarding appropriate control of diabetes mellitus and also the importance of treatment regarding tuberculosis.

Possible risks:
Methods applied to do the study are safe. No risk is involved in the study.

Cost of participation:
The cost of the study will be borne by the researcher. You will not have any costs attached to your participation.

Legal rights:
By signing this consent form you are not waiving any of your legal rights.

Privacy and Confidentiality:
The results of the study may be published in journals for scientific purposes. However your identity will not be revealed. All information collected will be coded so that no one other than the investigator will know your identity.

Withdrawal from the study:
You are requested to participate in the study and your participation is completely voluntary and you can withdraw from the study at any time you wish to do so. You may choose not to enrol in this study and your decision will not change present or future health care services offered to you.

Authorization to publish the results:
The researcher may use the information gathered from this study for presentation in scientific meetings. However your identity will not be revealed.

Queries:

If you have any queries regarding the study, If you have any questions about rights as a research participant you can contact Dr V. D. Patil, Principal and Chairman, Jawaharlal Nehru Medical College Institutional Ethics Committee on human subjects' research on 0831-2471701.

Consent summary:

I have been explained all the contents of this consent form in my local language and having understood and clarified all my queries about the study to the best of my knowledge, I hereby give my voluntary consent for participation in the study. I do sign the informed consent form in front of an eyewitness whom I recognize.

Name and Signature/ left thumb impression of the participant:

Name and Signature of the interviewer:

Name and Signature/ left thumb impression of the eyewitness:

Signature of the guide:
Date:

ANNEXURE V – KEY TO MASTER CHART

General Information

A. Serial Number

B. Age (in completed years)

C. Sex

1. Male
2. Female

D. Occupation

1. Professional
2. Semi professional
3. Clerk, shop owner, farmer
4. Skilled worker
5. Semi skilled worker
6. Unskilled
7. Unemployed
8. House wife

E. Religion

1. Hindu
2. Muslim

F. Education

1. Illiterate
2. 1^{st} to 5^{th} standard
3. 6^{th} to 10^{th} standard
4. PUC
5. Graduate
6. Post graduate

G. Marriage

1. Unmarried
2. Married

3. Widow/widower
4. Divorcee

H. Type of family

1. Nuclear
2. Joint
3. Extended
4. Broken

I. Socio-economic status. (According to Modified B. G. Prasad's classification)

1. Class I
2. Class II
3. Class III
4. Class IV
5. Class V

J. Ventilation

1. Good
2. bad

K. Overcrowding

1. Absent
2. Present

L. Cough

0. Absent
1. Present

M. Fever

0. Absent
1. Present

N. Hemoptysis

0. Absent
1. Present

O. Dysnoea

0. Absent
1. Present

P. Weight loss

0. Absent
1. Present

Q. Night sweats

0. Absent
1. Present

R. Symptom scoring

Add L+ M+ N +O+ P+ Q+S

S. Appetite

0. No change
1. Increased
2. Decreased

T. Tobacco

0. Not used
1. Present user
2. Past user

U. Alcohol

0. Not alcoholic
1. Present user
2. Past user

V. Diet

1. Vegetarian
2. Mixed

W. Physical activity: Job related/ Leisure time related

1. Sedentary
2. Moderate
3. Heavy

X. Family history of TB

0. No
1. yes

Y. Family history of DM

0. No
1. Yes

Z. Height in metres

AA. Weight in Kgs

AB. BMI

AC. Waist circumference in cms

AD. Type of TB

1. Pulmonary
2. Extra pulmonary

AE.. Category of TB

1. CAT 1
2. CAT 2

AF. Retreatment case type

0. Not retreatment
1. Relapse
2. Failure
3. Treatment after default

4. Others

AG. Sputum Result

0. Negative
1. 1+
2. 2+
3. 3+
4. Scanty

AH. HIV status

0. Not known
1. Reactive
2. Non- reactive

AI. History of DM, ie Known case

0. No
1. Yes