STUDY TO DETERMINE THE PREVALENCE OF DIABETES MELLITUS AMONG NEWLY DETECTED SPUTUM POSITIVE TUBERCULOSIS PATIENTS IN VIJAYAPURA TALUK VIJAYAPURA DISTRICT.

By

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Under the guidance of

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LIST OF ABBREVIATIONS

ADA	– American Diabetic Association
BMI	– Body Mass Index
CP	– Continuation Phase
DM	– Diabetes Mellitus
DMTB	– Diabetes mellitus and tuberculosis
DOTS	– Directly Observed Treatment Short Course
DTC	– District Tuberculosis Unit
HbA1c	– Glycated Haemoglobin
HIV	– Human Immuno-Deficiency Virus
GOI	– Government of India
IP	– Intensive Phase
MDR-TB	– Multi-Drug Resistant TB
NPCDCS	– National Programme for Prevention of Cancer, Diabetes, Cardiovascular disease and Stroke
PHC	– Primary Health Centre
RBS	– Random Blood sugar
RNTCP	– Revised National Tuberculosis Control Programme
STLS	– Senior Tuberculosis laboratory Supervisor

STS – Senior Treatment Supervisor

TB – Tuberculosis

TU – Tuberculosis Unit

WHO – World Health Organization

ABSTRACT

Background & Objective: Tuberculosis (TB) and diabetes mellitus (DM) is merging epidemic in India. Every fourth TB patient is an Indian and India is known as 'the diabetic capital of the world'. Though there are many theoretical hypotheses for TB as risk factor for DM, the exact pathophysiology is unclear. The existing burden of this deadly combination in this part of Karnataka is not known. Hence this study was conducted with a primary objective to find the prevalence of diabetes mellitus among cohort of tuberculosis patients registered under RNTCP in Vijayapura Tuberculosis Unit during the calendar year 2016. Secondary objective is to assess the risk factors of diabetes mellitus among tuberculosis patients.

Methodology: A cross sectional study was conducted among all new sputum positive pulmonary TB patients aged 18 years above, registered in Vijayapura Tuberculosis Unit. Sample of 215 TB patients were collected using interview technique. For those having symptoms of DM, random blood glucose level was noted. Mean, SD, Chi-square/Freeman-Halton Fisher exact test were done to find the association.

Results: Out of 215 TB patients, the prevalence of DM was 23.7% (2.8% known and 97.8% new cases). Among the risk factors age >46yrs, less educational status, were positively associated.

Conclusion: Most of the TB patients were not aware of their DM status. Screening of DM in all TB patients should be made mandatory because of the increasing prevalence of DM among TB patients.

Key Words: Diabetes Mellitus, Tuberculosis, Prevalence, Risk factors.

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INTRODUCTION

Tuberculosis (TB) is an infectious disease caused by Mycobacterium tuberculosis. It is most commonly transmitted by inhalation of infected droplet nuclei which are discharged in the air when a patient with untreated TB coughs or sneezes. TB disease usually affects the lungs, but can involve any part of the body. All those who get infected do not necessarily develop TB disease. The lifetime risk of getting disease among those infected with TB is 10-15%. Other determinants such as diabetes mellitus (DM), smoking tobacco products, alcohol abuse and malnutrition also increase the risk of progression from infection to TB disease.[1] The social factors like poor quality of life, poor housing, overcrowding, population explosion, under-nutrition, lack of education, large families, early `1marriages, lack of awareness of cause of illness also contribute to the occurrence and spread of tuberculosis.[2]

Diabetes is a heterogeneous group of diseases, characterised by a state of chronic hyperglycaemia, resulting from a diversity of aetiologies, environmental and genetic which act jointly.[2]

Several medical conditions like HIV, malnutrition and silicosis which are risk factors for TB and poor TB treatment outcomes. Similarly, TB can complicate course of some diseases. Therefore it is important to identify these co morbidities in order to ensure early diagnosis and improved outcome. When these conditions are highly prevalent in the general population they can be important contributors to the TB burden. Consequently, reducing the prevalence of these conditions can help prevent TB.[1]

As a result of urbanization as well as social and economic development, there has been a rapidly growing epidemic of DM. People with a weak immune system

such as diabetes, are at a higher risk of progressing from latent to active disease. So people with DM have a 2-3 times higher risk of getting TB compared to people without DM.[2]

Globally about 10% of TB cases are linked to DM.[1] A large proportion of people living with DM as well as TB are not diagnosed or diagnosed too late. Therefore early detection can help improve care and control of both diseases. DM can increase the time taken to sputum culture conversion and thus it leads to the development of drug resistance if a 4 drug regimen in the intensive phase is changed to 2 drug regimen after 2 months in the presence of culture positive TB.[1] People living with DMTB have a higher risk of death during treatment and risk of TB relapse after completing treatment. DM is complicated by the presence of infectious disease, including TB. It has been observed that good glycemic control in TB patients can improve treatment outcomes. Recent studies have shown that DM accounts for 20% of smear positive TB and have indicated that increase in DM prevalence in India has been an important obstacle in reducing TB incidence.[2]

TB and DM comorbidity is one of the rising public health problems. There is lack of literature regarding this comorbidity in our area. Therefore this study was conducted to know the prevalence of DM among TB patients in Vijayapura taluk.

OBJECTIVES

1. To study the prevalence of diabetes mellitus among newly detected sputum positive pulmonary tuberculosis patients registered in District Tuberculosis Centre during the calendar year 2016 .

2. To study the socio-demographic profile of tuberculosis patients with diabetes mellitus and to identify the risk factors.

REVIEW OF LITERATURE

History:

"TB Anywhere is TB Everywhere"

- By UNAIDS

Consumption, ***phthisis***, ***scrofula***, ***Pott's disease***, and the ***White Plague*** are all terms used to refer to tuberculosis throughout history.[3]

Evidence for tuberculosis infection was discovered in human remains from the Neolithic era (9000 years ago) in the eastern Mediterranean. This finding was confirmed by morphological and molecular methods which is the oldest evidence of tuberculosis infection in humans. It was also found in a cemetery near Heidelberg, in the Neolithic bone remains that showed the presence of angulation often seen with spinal tuberculosis. Some authors call tuberculosis the first disease known to mankind.[3]

Signs of the disease have also been found in Egyptian mummies dated between 3000 and 2400 BC. The most convincing case was found in the mummy of priest Nesperehen, discovered by Grebart in 1881, which had the characteristic psoas abscesses. Similar features were discovered on other mummies and throughout the cemeteries of Thebes. It appears likely that Akhenaten and his wife Nefertiti both died from tuberculosis, and evidence indicates that hospitals for tuberculosis existed in Egypt as early as 1500 BC.[3]

The first reference of tuberculosis in non-European civilization is found in the Vedas. The oldest of them *Rigveda* (1500 BC) calls the disease as *yaksma*. The *Atharvaveda* calls it as *balasa*. It is in the *Atharvaveda* that the first description of the disease is given. The Sushruta Samhita, which is written around 600

BC, recommends that the disease can be treated with breast milk, various meats, alcohol and rest.[3]

Diabetes is one of the first diseases described in an Egyptian manuscript mentioning “too great emptying of the urine”. Indian physicians around the same time identified the disease and named it as *madhumeha* or *honey urine* noting that the urine would attract ants. The term "diabetes" or "to pass through" was first used in 250 BC by the Greek Apollonius of Memphis. Type 1 and type 2 diabetes were identified as separate conditions for the first time by the Indian physicians Sushruta and Charaka, type 1 associated with youth and type 2 with obesity. The term "mellitus" or "from honey" was added by Thomas Willis in the late 1600s to separate the condition from diabetes insipidus which is also associated with frequent urination.[4]

The association between these two clinical entities was first reported by Avicenna in 980–1027 AD.[5] In the early part of the 20th century, clinicians have observed an association between DM and TB, though they were unable to determine whether DM caused TB or whether TB led to the clinical manifestation of DM. The mid 20th century saw a few reports documenting such a link and its significance.

Recently, many rigorous epidemiological studies investigating the relationship have demonstrated that DM is indeed positively associated with TB. These observations raise the important scientific and public health questions concerning possible immunological mechanism.

Epidemiology of Diabetes mellitus:

Global scenario:

According to the latest 2016 data from the World Health Organization (WHO) globally, 422 million adults are living with diabetes mellitus. The prevalence is increasing rapidly and the number is projected to almost double by 2030. About 85-90% of them have type 2 diabetes mellitus. Increase in the diabetes prevalence rate is due to increase in risk factors, greater longevity and overweight.[6]

Diabetes mellitus is present throughout the world, but is more common (especially type 2) in the developed countries. Nowadays the increase in prevalence is seen more in low and middle-income countries including Asia and Africa. This increase in developing countries is due to urbanization and lifestyle changes, including sedentary lifestyles, less physically demanding work and the global nutrition transition marked by increased intake of foods that are high energy-dense but nutrient-poor (often high in sugar and saturated fats, referred to as the western pattern diet). The risk of getting type 2 diabetes has been widely associated with lower socio-economic class across countries. The WHO estimates that diabetes resulted in 1.5 million deaths in 2012, making it the 8th leading cause of death.[6]

Indian scenario:

Until recently, India had more diabetics than any other country in the world, according to the International Diabetes Foundation, although the country has now been surpassed in the top spot by China. Diabetes currently affects more than 62 million Indians, which is more than 7.1% of the adult population. The average age of onset is 42.5 years. Nearly 1 million Indians die due to diabetes every year. According to the Indian Heart Association, India is projected to be home to 109 million people with diabetes by 2035. The high incidence is due to genetic susceptibility as well as

adoption of a high-calorie diet, low physical activity by growing middle class of India.[6]

Epidemiology of Tuberculosis:

Global scenario:

In 2015, there were an estimated 10.4 million new TB cases worldwide. Six countries accounted for 60% of the new cases: India, Indonesia, China, Nigeria, Pakistan and South Africa and there were an estimated 1.4 million TB deaths. Although the number of TB deaths fell by 22% between 2000 and 2015, TB remained one of the top 10 causes of death worldwide in 2015. Notified TB cases increased from 2013–2015, mostly due to a 34% increase in notifications in India.[7] However, globally there was a 4.3 million gap between incident and notified cases, with India, Indonesia and Nigeria accounting for almost half of this gap.[8]

Indian scenario:

India accounts for 1/4th of the global TB burden i.e 2.2 million out of 9.6 million new cases annually. In India more than 40% of population is infected with Mycobacterium tuberculosis. It is estimated that there are 2.5 prevalent cases of all forms of TB disease. About 2.2 lakhs people die due to TB annually. TB kills more adults in India than any other infectious disease. In India, everyday more than 6000 people develop TB disease, more than 600 people die of TB (i.e. 2 deaths every 5 minutes).[1]

To combat the disease burden of TB, its morbidity and mortality, the Government of India started the national health programme, which has undergone

many changes according to the drawbacks of each one. The evolution of the programme is as follows:

Evolution of TB Control programme in India[1,2]

1962: National Tuberculosis Programme (NTP)

1993: Revised National Tuberculosis Control Programme (RNTCP) in population of 2.4 million of 5 states

1995: RNTCP expanded to cover 13 million people

1996: Later expanded to cover 20 million

1997: RNTCP adopted the internationally recommended DOTS (Directly Observed Treatment Short-course)

2006: India adopted the components of STOP TB Strategy

2012-17: National Strategic Plan with a vision of TB Free India

2012: GOI mandates all healthcare providers to notify every TB case diagnosed and/or treated, to local authorities.

2014: Standards for TB Care in India (STCI)

2015: End TB Strategy

In the recent years the programme has been fighting with the challenges given by the presence of co morbidities in TB such as HIV and DM. To reduce TB and DM comorbidity in India the national strategy has found some of the collaborative activities between National programme for prevention of cancer, diabetes, cardiovascular diseases and stroke) NPCDCS and RNTCP.

National Framework for Joint TB-DM collaborative activities:[1,9,10]

The proposed collaborative activities between NPCDCS and RNTCP are as follows:

1. Establishing joint planning and review committee for collaboration at National, State and District levels.
2. Establishment of service delivery protocols that address joint activities is as follows:

   a. Activities to improve diagnosis and management of Diabetes among TB patients:

   i) Screening of all registered TB patients for DM

   ii) Ensuring DM management among TB patients

   b. Activities to improve diagnosis and management of TB among diabetic patients:

   i) Intensified detection of active TB disease among DM patients

   ii) Ensuring TB infection control measures in health care settings where DM is managed

   iii) Ensuring TB treatment and management in co morbid patients.
3. Joint monitoring and evaluation with standardized reporting shared between NPCDCS and RNTCP
4. Joint training of key programme and field staff in DM /TB activities
5. Awareness and IEC activities
6. Operational research to strengthen implementation of DM/TB collaborative activities[1]

Recent initiatives:

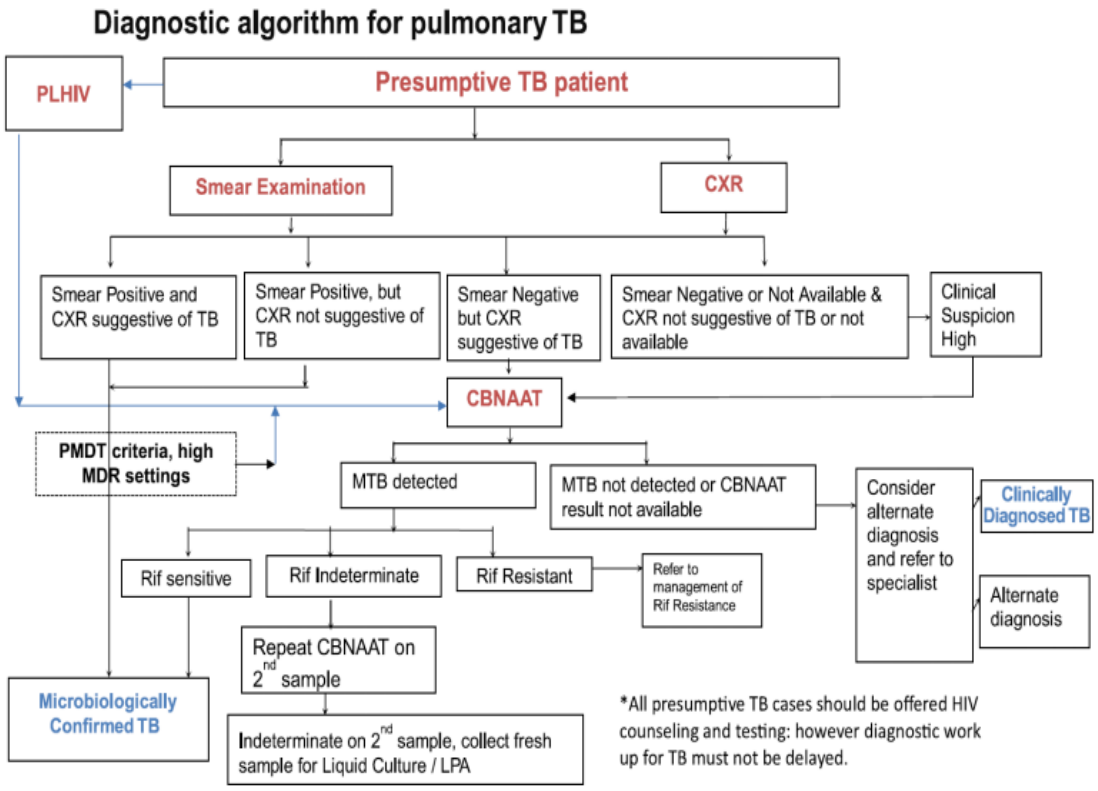
Definition of presumptive TB:[1,2]

The definition has changed from TB suspect to presumptive TB, now presumptive pulmonary TB refers to a person with any of the symptoms and signs suggestive of TB including cough for >2 weeks, fever >2 weeks, significant weight loss, haemoptysis, any abnormality in chest radiograph.

Note: In addition, contacts of microbiologically confirmed TB patients, people living with human immune deficiency virus (PLHIV), diabetics, malnourished, cancer patients, and patients on immune suppressants or steroids should be regularly screened for signs and symptoms of TB.

The diagnostic algorithm for TB has been changed which has made all the patients to undergo CBNAAT (cartridge based nucleic acid amplification test). Presently, under RNTCP, CBNAAT is recommended for diagnosis of drug resistant TB patients and TB in key population such as children, PLHIV and extra-pulmonary TB.[1,2]

Fig 1. Flowchart showing the diagnostic algorithm for pulmonary TB[1,2]



Smear positive and presumptive multidrug resistant (MDR) TB and in settings of high MDR TB, CBNAAT will be done to rule out Rif (rifampicin) resistance. If the first smear is negative, chest x-ray (CXR) is considered and if reported as positive, the second sample will be subjected to both smear and CBNAAT.

If the both sputum smears and CXR are negative and still physician has high suspicion, he will refer the patient to pulmonologist. All key population (PLHIV, children, EPTB etc.) will undergo CBNAAT as per approved algorithm.

The algorithm will not decide the "order to DO" the investigations. If needed, appropriate tests may be done simultaneously but "order of consideration" for different types of investigation results should be as per the algorithm.[1]

Treatment of TB:[1,2]

The programme is now introducing daily regimen for treatment of all drug sensitive TB patients in 104 districts initially. The principle of treatment for TB with daily regimen is to administer daily fixed dose combinations of first line anti-TB drugs in appropriate weight bands. For new TB cases the treatment in intensive phase (IP) will consist of 8 weeks of isoniazid, rifampicin, pyrazinamide and ethambutol in daily dosages as per 4 weight band categories. There will be no need for extension of IP. Only pyrazinamide will be stopped in the continuation phase (CP), while the other 3 drugs will be continued for another 16 weeks as daily dosages.

Table 1. Daily Dose Regimen for Adults (as per weight bands)[1,2]

Type of TB case	Treatment Regimen in IP	Treatment Regimen in CP
New	(2) HRZE	(4) HRE
Previously treated	(2) HRZES+(1) HRZE	(5) HRE

Prefix to the drugs stands for number of months, all drugs are given under supervision.

(H-Isoniazid, R-Rifampicin, Z- Pyrazinamide, E- Ehambutol, S- Streptomycin)

Table 2. Fixed Dose Combination (FDC) for adult TB patient[1,2]

Weight category	Number of tablets (FDCs)		Inj. Streptomycin
	Intensive phase	Continuation phase	
	HRZE	HRE	
	75/150/400/275	75/150/275	Gm
25-39 kg	2	2	0.5
40-54 kg	3	3	0.75
55-69 kg	4	4	1
≥70 kg	5	5	1

*Injection Streptomycin to be added in IP phase for 2 months in the previously treated regimen of drug sensitive patients.

In patients above 50 years of age, maximum dose of streptomycin should be 0.75 gm.

Adults weighing less than 25 kg will be given loose drugs as per body weight.

End TB Strategy:[2,10]

This recent programme has the **vision** of a world free of TB-zero deaths, disease and suffering due to TB and **goal** as to end the global TB epidemic.

Table 3. Indicators, milestones and targets of End TB Strategy[2,10]

Indicators	**Milestones**		**Targets**	
	2020	2025	SDG 2030	END TB 2035
Reductions in number of TB deaths compared with 2015 (%)	35%	75%	90%	95%
Reduction in TB incidence rate compared with 2015 (%)	20%	50%	80%	90%
TB-affected families facing catastrophic costs due to TB (%)	Zero	Zero	Zero	Zero

SDG: Sustainable development goals.

Pathogenesis of Tuberculosis in Diabetes Mellitus:

It was observed that the lowering of cellular immunity was an important factor for increased incidence of tuberculosis in diabetes. Experimentally, it was shown that dogs lost their natural resistance to tuberculosis after pancreatectomy and the resistance of albino rats lowered after inducing hyperglycemia. Increased availability of glycerol may be responsible for multiplication of bacilli. In diabetes, pulmonary tuberculosis showed special features like large confluent lesions which tend to liquefy extensively. Malnutrition plays a role in the lowering of metabolic activity, thereby leading to the progress of disease. In addition, hepatic dysfunction with demonstrable depletion of glycogen and consequent hypovitaminosis may play a major role in the causation of tuberculosis in diabetic patients. Overproduction of adrenocorticotropic hormone (ACTH) and consequent rise in corticosteroids may results in enhanced exudative inflammatory response and reduces granulation tissue formation.[11]

There are decreased T lymphocytes and neutrophil count in diabetics. A reduced T-helper1 (Th1) cytokine response level, TNF alpha production, and IL-1 beta and IL-6 production is also seen among people having both diabetes and TB as compared to non diabetic individuals. Th1 cytokines play a major role in the control and inhibition of mycobacterium tuberculosis bacilli. This decrease in T lymphocyte number and function is primarily responsible for the susceptibility of diabetics to TB. Macrophage function is also inhibited in individuals with diabetes, with an impaired production of reactive oxygen species, phagocytic and chemotactic factors. Hyperglycemia has deleterious effect on the respiratory burst. A combination of these pathophysiological processes are responsible for an increased risk of TB in diabetes.[12]

Table 4. Studies on Prevalence of Diabetes Mellitus in India

Author	Study Type	Place	Year	Prevalence
Sangral R *et al*[13]	Community based observational study	Jammu	2012	8.2%
Balakrishnan S *et al*[14]	Cross sectional	Kerala	2012	23%
Viswanathan V *et al*[15]	Cross sectional	Tamil Nadu	2012	25.3%
Khanna A *et al*[16]	Descriptive study	New Delhi	2013	14%
Dutt N *et al*[17]	Cross sectional	Ahmadabad	2014	20.24%
Padmalatha P *et al*[18]	Institutional based cross sectional	Andhra Pradesh	2014	30.6%
Mansuri S *et al*[19]	Facility based cross sectional	Ahmadabad	2015	15.3%
Natarajaboopathy R *et al*[20]	Cross sectional	Tamil Nadu	2016	38.6%
Tiwari V K *et al*[21]	Observational cum descriptive study	Delhi	2016	16%
Raghuraman S *et al*[22]	Facility based cross sectional	Pondicherry	2017	29%
Mahishale V *et al*[23]	Hospital based prospective study	Belgaum, Karnataka	2017	40%

Related studies:

A cross sectional hospital based study done by Damtew E *et al* (2014) at St Peter specialised hospital, Addis Ababa, Ethiopia revealed that out of 120 active pulmonary tuberculosis patients the prevalence of diabetes was 15.8% (new cases 84.2%). Male TB patients were higher (25.4%) than female TB patients (3.8%). 70% of the patients were from urban and 30% of them were from rural areas and all the diabetic patients were more than 25 years of age.[24]

A facility based cross sectional study in South-Eastern Amhara Region, Ethiopia by Workneh MH *et al* (2016) showed that out of 1314 patients, the prevalence of DM was 109 (8.3%). The female patients age 65–89 years, a pulmonary TB case and having a family history of DM were associated factors.[25]

There were 271 cases of TB among 802087 members of the DM cohort and 130 cases of TB among 273023 people using insulin in a cohort study done by Dobler CC *et al* (2012) in Australia. The percentage of Australian-born people was slightly higher in the DM population.[26]

A cross sectional study done by Al-Adhami SB *et al* at Al-Yarmouk teaching hospital in Baghdad-Iraq (2004) showed that the prevalence as 56%. And the male to female ratio was 5:1. 16% of the patients were of type 2 diabetes mellitus.[27]

Out of 102 TB cases, prevalence of DM was 22.5% in a facility based cross sectional study done in Batticaloa district, Sri Lanka by Umakanth M *et al* (2017). Half of the TB patients (50%) were underweight.[28]

1. Li L *et al* (2012) did a prospective observational study in China, which showed that out of 8886 registered TB patients, DM prevalence was 12.4% (9.7% known and 2.9% new cases).[29]
2. In a study done by FJ Danielin Tanzania (2012), showed that the prevalence of diabetes was 16.7%. And the mean age was 34.8 yrs.[30]
3. The DM prevalence among TB patients ranged from 5% to >50%, and the TB prevalence among diabetic patients was 1.8–9.5 times higher than in the general population in a review study done by Zheng C *et al* (2017) in developing Asian countries.[31]

A retrospective study done in the Eastern Saudi Arabia by Chaudhry LA *et al* (2012) showed that among 1388 patients, 7.17% had type-2 diabetes mellitus. Of these diabetics, majority (79.82%) were Filipinos. Sputum conversion was late in diabetic patients which resulted in relatively longer hospital stay.[32]

In a study done by MM Mandzisi (2016) in the State of Florida, USA, the prevalence of DM among TB patients was 12% and it was 16.5 % among people > 40 years.[33]

In a case control study done by Alisjahbana B *et al* in Indonesia (2006), the prevalence of Diabetes mellitus was 13.2% out of 454 TB patients. They had median age of 30 years and 52% were males, but malnutrition was more common among TB patients.[34]

In a retrospective descriptive study by Jabbar A *et al* (2006) in Pakistan, 173 patients had both tuberculosis and diabetes out of 42358 patients. The prevalence of tuberculosis in diabetic patients was 10 times higher and increased with duration of diabetes.[35]

Tahir NB *et al* (2014) did a descriptive study in Kohat, out of 253, 44.26% were males and 55.73% were females. 18.97% patients had blood glucose levels more than 200mg/dl and 25.69% patients had blood glucose levels between 150-200 mg/dl. The incidence of diabetes mellitus was more in tuberculosis patients.[36]

A cross sectional study conducted by Olayinka AO *et al* (2013) in Lagos, Nigeria, the prevalence of DM among TB patients was 5.7%. The mean age of the participants was 34.9 ± 13.21 years. Weight loss was the most predominant (94%) symptoms among the patients.[37]

In a similar cross sectional study from Pakistan by Tahir Z *et al* (2016), the prevalence of DM among TB patients was 14.8%. It was higher (62.2%) among males and in patients (35.1%) more than 57 years. Most of the patients were illiterate (73.0%) and unemployed (48%). 74 patients had a history of smoking. Age and education level were significantly associated with DM-TB.[38]

A study done by Amin S *et al* in Peshawar (2011), out of 100 diabetic patients 54 were males and 46 females. The prevalence of tuberculosis was 14%. Fever was the commonest presenting symptom of tuberculosis (75%), followed by cough (56%), and hemoptysis (17%).[39]

In a cross sectional hospital based study done by Noureen in Rawalpindi, Pakistan (2017), out of 248 patients 51% were males and 49% were females. The mean age was 42 years. The prevalence of diabetes was 21% (7.28% new cases) in TB patients. They were in their productive age group. Weight loss and malnutrition was the predominant symptom (91%). Majority patients were belonged to rural areas with monthly income less than 10,000.[40]

A multi-centre implementation study carried-out in 13 health facilities in six States of Southern Nigeria by Ekeke N *et al* (2017) showed that, of the 2094 patients, 196 were found to have DM (3.9% known cases and 5.5% newly diagnosed). The prevalence of DM 16.9% among those aged 46–55 yrs. The prevalence of DM was 13.3% among rural residents compared to 5.7% among urban residents. Similarly, the prevalence was high among patients who received care at a private facility compared to public facility. The prevalence among patients with sedentary occupation was 10.2%.[41]

Among 158 tuberculosis patients, the DM prevalence was 25.9% (5.69% newly diagnosed). 60.8% patients were in the age group of 35–55 years and 61.4% were male patients. Most (74.7%) of them belonged to rural areas while 72.8% patients were illiterate and 88% had monthly income less than 7000 PKR, in a cross sectional study done at tertiary care hospital of Lahore by Usmani RA *et al* (2016).[42]

A cross sectional study by Kibirige D *et al* in Uganda (2013) showed that of the 260 study participants, majority were males (56.2%). The mean age was 34.5 years. The prevalence of diabetes was 8.5% (1.9% known case of diabetes mellitus). Majority (90.9%) of the study participants had type 2 diabetes mellitus.[43]

In a community based cross-sectional quantitative study done by Sarker M *et al* in Bangladesh (2016) showed that out of 1910 TB patients, 12.8% were diabetic. Older age, higher BMI, higher education (secondary level and above), being married, less physical activity, and family history of diabetes were associated with higher prevalence of diabetes.[44]

In a study done by Reis-Santos B *et al* in Brazil (2013) reported that TB-DM patients were older, had initial sputum smear test positive and many died due to TB. They were less institutionalized; developed extra pulmonary TB.[45]

A retrospective cohort study done by Gil-Santana L *et al* (2016) in Brazil said that DMTB patients were older and the diabetic individuals more frequently presented with cough, night sweats, hemoptysis and malaise. The TB severity score was significantly associated with TB-diabetes comorbidity.[46]

In a population based case control study done by Leegaard A *et al* in Denmark (2011) there were 2950 patients of whom 156 were diabetics along with active TB, the adjusted OR was 1.18.[47]

A prospective cohort study done by Mukhtar F *et al* in Pakistan (2016) had greater proportion of DMTB patients as illiterate. Unfavourable treatment outcome was more among patients with diabetes as compared to patients without diabetes.[48]

In a study done by Gnanasan S *et al* in Penang Malaysia (2011) reported that the prevalence of diabetes mellitus among newly diagnosed tuberculosis patients as 15%. Patient's mean age was 52 ± 10 years. The male: female ratio was 1.7:1.[49]

A population based cohort study in Mexico by Ponce-de-Leon A *et al* in 2004 showed that the prevalence of diabetes among tuberculosis patients as 5.3%. The rates of tuberculosis were greater for patients with diabetes compared to non diabetic individuals.[50]

Kang YA *et al* (2013) did a study in South Korea revealed that out of 1,407 patients 17.0% had coexisting DM. The mean age and body mass index were higher in them. Patients with comorbidity of DM had a significantly lower treatment success. In multivariate analysis, DM was the negative predictor for MDR-TB treatment success. Mean survival times were also lower in them, with DM as a significant predictor of poor long-term survival.[51]

In a case control study done by Perez-Navarro LM (2015) *et al* in Southern Mexico showed the associated factors with the presence of type 2 diabetes mellitus were age ≥35 years, previous contact with a person infected with

tuberculosis. Body mass index ≥25 kg/m^2, and inherited family history of diabetes. And also said that patients with tuberculosis–type 2 diabetes mellitus had a 4.7-fold and 3.5-fold higher risk of developing drug-and multidrug resistance tuberculosis, respectively. Individuals with both tuberculosis and type 2 diabetes had a 2.3-fold greater chance of persisting as tuberculosis positive by the second month of treatment, which delayed the solution of tuberculosis infection.[52]

In a study done by Chiang CY *et al* in Taiwan (2015) told that in multivariate analysis adjusted for age, sex, smoking, and drug resistance, diabetic patients with HbA1C >9% and HbA1C 7–9% were smear positive as compared with non-diabetic patients. Patients with diabetes-related co morbidities had an increased risk of unfavourable outcome.[53]

In a study done by Natarajaboopathy R in Chengalpattu (2016) the prevalence of diabetes and pre-diabetes among TB patients were 38.6% and 18.9% respectively. The male: female ratio was significantly high in diabetic and pre-diabetic TB patients. Family history of DM was high among DMTB patients.[20]

An institutional based cross sectional study done by Padmalatha P in Guntur, Andhra Pradesh (2014) showed that of the total 252 tubercular patients, the overall prevalence of Diabetes mellitus was 30.6% (77.8% were newly diagnosed cases). Increasing age, Body Mass Index (BMI), systolic blood pressure and category of TB treatment were significantly associated with DMTB patients.[18]

Out of 280 tuberculosis cases registered, 65.3% were males & 34.6% were females. Approximately two third (58%) of the patients were in the age group of 31 - 60 years. Majority of the patients (61.7%) belonged to lower and lower middle socio-economic class. 69% of the patients were sputum positive and it was higher among males. The prevalence of DMTB was 8.2% in a community based observational study conducted in a rural population of Jammu (2012) by Sangral R *et al*.[13]

A cross sectional study done by Balakrishnan S *et al* in Kerala (2012) showed that among 552 TB patients screened, 44% had DM – 23% were known case of DM and 21% were newly diagnosed. The prevalence was high among males and those aged >50 years. Among DMTB patients 84% had poor glycemic control.[14]

A prospective observational study conducted by A Kumar *et al* (2013) in India showed that out 254 TB patients 46% had smear positive pulmonary disease (18 patients newly diagnosed). TB case rates per 1000 patients attending the DM clinic each quarter were 859, 956 and 642.[54]

In a hospital based descriptive study conducted by Kottarath MD *et al* in Pariyaram, Kerala (2015) showed the prevalence of diabetes as 19.6% which was higher among tuberculosis patients compared to general population. It was significantly associated with older age, higher BMI and sputum positivity.[55]

In a study done by J Kishan *et al* in Patiala, Punjab (2010) showed the age group most commonly involved as 40-60 years of which 61 were males. Majority had diabetes diagnosed before the diagnosis of tuberculosis, 23 had diagnosis after TB diagnosis, and 20 simultaneously with TB diagnosis. Out

of these 57 diagnosed diabetics, 11 patients had controlled diabetes whereas 46 had uncontrolled diabetes.[56]

In a prospective study done by Babu RV *et al* in Puducherry (2013) reported 22 out of 378 proven cases of pulmonary tuberculosis, were diabetic. All patients had symptoms of cough with expectoration and weight loss. 95.5% patients had fever, 59.1% had breathlessness, 31.8% had non-specific chest pain and 9.1% had hemoptysis.[57]

In a study done by Dutt N *et al* in Ahmedabad (2014), it was found that majority of patients were males and the age group most commonly involved was 40-60 years. Most (48) of them were diagnosed as diabetics before the diagnosis of tuberculosis, 19 were diagnosed after TB diagnosis .Out of these 48 diagnosed diabetics, 9 had controlled and 39 had uncontrolled blood glucose levels.[17]

In a study done by Tiwari VK *et al* in Delhi (2016) the prevalence of DMTB was 16%. Among co-morbid patients, the age distribution skewed towards higher age groups as compared with only TB patients. It was higher among females (64%). Most of the co-morbid patients (78%) belonged to lower socio-economic class. Physical activity, dietary habits and tobacco/alcohol consumption were significantly associated with comorbidity.[21]

In a study done by Viswanathan V *et al* in Tamilnadu (2012) reported the DM prevalence as 25.3% and that of pre-diabetes as 24.5%. Risk factors associated with DM among TB patients were age, positive family history of DM, sedentary occupation, and BMI. DM risk was higher among sputum positive pulmonary TB.[15]

A facility-based cross section study was undertaken in urban health centre Ahmedabad by Mansuri S *et al* (2015) showed that out of 85 patients, 59% were males and 41% were females. The mean age of TB among diabetics was 47 ± 16 years. The prevalence of diabetes among TB patients was 15.3%. Out of 85 TB patients most (55) of them belonged to Category I.[19]

MATERIAL AND METHODS

Source of data: Vijayapura district covers 4,070 sq km and population of 2,206,918. It consists of 5 Tuberculosis Units (TU) namely Vijayapura, Basavan Bagewadi, Muddebihal, Sindagi and Indi. The present study was undertaken in the Vijayapura TU. Tuberculosis register was used to approach the TB patients.

Study population: Patients registered in Vijayapura TU during 4 quarters of the year 2016 was the study population. Vijayapura TU covers 14 primary health centres (PHCs) (Babaleshwar, Tikota, Honnutagi, Nagthan, Kannur, Mamadapur, Honawad, Kanamadi, Kakhandaki, Yakkundi, Honaganahalli, Kambhagi, Shivanagi, Jainapur) and 4 Urban health centres (UHCs) (Darga, Yogapur , Shantinagar, Navbagh) and 2 medical colleges.

Study design: Cross sectional study

Study technique: Interview technique

Study Period: January 2016 – January 2017

Sample size: All newly detected sputum positive TB cases of Vijayapura taluk registered from January 1st to December 31st 2016, at Vijayapura District Tuberculosis Centre (DTC) were included. Considering the prevalence of diabetes mellitus among tuberculosis patients to be 30.6%[18], at 95% confidence level and at 20% allowable error, the sample size is calculated by using the formula

$$n = \frac{Z^2 \times p \times q}{d^2} = 215$$

Inclusion Criteria:

1. The newly detected sputum positive pulmonary TB patients (18 years and above) registered in DTC during 4 quarters of the year 2016.

Exclusion Criteria:

1. Patients who are not willing to participate in the study.
2. Patients who are critically ill.
3. Pregnant and lactating women.
4. If the patient couldn't be found after 3 consecutive home visits.

Methodology:

After obtaining ethical clearance from the Institutional Ethical Committee the study was conducted in Vijayapur taluk. The study sample was drawn from DTC Vijayapur, after taking permission from District Tuberculosis Officer. Last week of every month there was a visit to the DTC. Name and address of newly detected sputum positive TB patients were collected from Tuberculosis register. Health workers/ASHAs were involved in the study. Objectives were explained to them.

The purpose and overview of the study was explained at the time of the interview, and interviewers were informed that, their participation was voluntary, their anonymity would be assured, they could withdraw from the study at any point of time and the information that they will be providing would be used solely for the purpose of the study. Confidentiality about data and findings were assured to the participants and their consent was taken.

The TB patients were approached at their homes/DOTS centres/PHCs with the help of Senior Treatment Supervisor. Procedure included 3 parts i.e., interview through semi structured questionnaire, anthropometric measurements and blood glucose estimation.

All TB patients having symptoms of DM were examined for random blood glucose level in a laboratory in respective PHC. Those found having both TB and DM, that patient's house was revisited and health education was given.

Instruments used for data collection:

The instruments used in our study included a semi structured questionnaire and instruments needed for general physical examination and blood glucose estimation.

Questionnaire: TB patients will be interviewed using semi structured and pretested questionnaire with modifications relevant to local conditions. It included information on

i) Socio-demographic variables

ii) TB treatment outcome of both present and past if any

iii) DM, its treatment if any, if not, the risk factors and symptoms of DM.

iv) Past, personal, family history and physical activity.

v) Results of general physical examination.

vi) Results of blood glucose estimation.

Instruments used for general physical examination: The instruments used in this study included a measuring tape, weighing machine, and stethoscope. All these instruments were regularly standardized throughout the period of data collection.

Instruments used for blood glucose estimation: All TB patients having symptoms of DM were examined for random blood glucose in a laboratory.

Study variables:[58]

- ✓ **Age:** Age was recorded in completed years as revealed by the subjects.
- ✓ **Marital status:** Marital status of the person was recorded under the following headings.
    1. Never married: Person never been married any time before.
    2. Married: Person currently married, whether for the first time or another time and whose marriage is subsisting at the time of study.
    3. Widowed: Person whose partner has been died and he/she has not married thereafter during the time of the study.
- ✓ **Place:**
    - ➢ Urban: The urban area of the country was defined as follows:

1. All places with municipality, corporation or cantonment and places notified as town area

2. All other places which satisfied the following criteria:

a. A minimum population of 5000

b. At least 75% of the male working population are non-agriculturists

c. Density of population of at least 400 persons per sq. km

- ➢ Rural: The rural sector covers area other than the urban areas.

- ✓ **Type of family:**
  - Nuclear family: It consists of a married couple and their children while they are still regarded as dependents.
  - Joint family: It consists of number of married couple and their children living together in the same household. All men are related by blood and women of household are their wives, unmarried sisters and their family kinsmen.
  - Three Generation family: It is a family where representatives of three generation are living together. Young married couple continue to stay with their parents and have their own children as well.
- ✓ **Education:**
  - Illiterate : Not able to read, write and understand in any language
  - Primary school: Studied up to 7^{th} standard
  - High school: Studied up to 8^{th} standard to SSLC
  - PUC/Diploma : Studied up to PUC or any diploma
  - Graduate and above: Studied up to graduation and above
- ✓ **Occupation:**
  - Home-maker: involved only in household chores.
  - Self employed: small businessman, shopkeeper, domestic servant.
  - Non government employee: Factory worker, labourer, Salesman etc
  - Government employee: Clerk, typist, teachers etc
- ✓ **Socio-Economic status:**[59]
  - Self- reported per capita monthly income was recorded. Modified BG Prasad's classification was used to assess the social class of the study subjects.

- Correction factor = $\frac{\text{Current Index value}}{\text{Base Index value (100)}}$

$= 277/100 = 2.77$

- Multiplication factor = Correction factor X 4.63 X 4.93

$= 2.77 \text{ X } 4.63 \text{ X } 4.93 = 62.61$

- This MF obtained is multiplied with the income limits of B G Prasad's classification 1961. Socio-economic classes obtained were as follows:

Table 5.Socioeconomic categories of modified B G Prasad's classification.[59]

Socio-economic class	B.G Prasad's classification(1961)	Modified B.G Prasad's classification(June2016)
Upper	Rs 100 & above X MF	6346 & above
Upper middle	Rs 99- 50 X MF	3173-6345
Lower middle	Rs 49-30 X MF	1904-3172
Upper lower	Rs 29-15 X MF	952-1903
Lower	Rs<15 X MF	Below 951

- ✓ **Habits:**
  - Tobacco consumption: Yes/No
  - Yes: Person who at the time of the data collection smokes/uses tobacco in any form either daily or occasionally for the past one year. (Smoke

form – cigarettes, bidis etc. Smokeless form – plug, loose leaf, chemo, tambak, gutkha etc)

- No: Person who at the time of the data collection does not smoke or use tobacco in any form either daily or occasionally for the past one year.

- ✓ Alcohol consumption: Yes/No
  - Yes: Person who at the time of the data collection drink any alcohol daily or occasionally for the past one year.
  - No: Person who at the time of the data collection does not drink any alcohol daily or occasionally for the past one year.

Measurement of height:[60]

For the measurement of height, study subjects were made to remove the footwear and stand with heels touching each other and toes apart and head positioned so that the line of vision was perpendicular to the body (Frankfurt line) against the wall. The arms were hung freely by the sides with the head, back, buttock and heels in contact with the wall. A wooden scale was brought down to the topmost point on the head and marking was made on the wall. Measurement was taken using measuring tape in centimetres (cm). Height was recorded to nearest 0.5 cm.

Measurement of weight: [60]

The weight was measured in kilograms (kg) using standardized bathroom weighing machine with the study subject standing erect on centre of platform, looking straight ahead with the body weight evenly distributed between both the feet but without footwear, with minimal clothing. The weight was recorded to nearest 0.5 kg.

Body Mass Index (BMI)[60]

In this study, BMI classification proposed by the WHO Western Pacific Regional Office in collaboration with IOTF (International Obesity Task Force) steering committee (2000) for Asian people was used. It is also called as Quetlet Index and was used to assess obesity and is computed by

BMI=Weight (in kg) / Height (in metre)^2

It is classified as BMI <18.5 (Under -weight), 18.5-22.9 (Normal), 23.0-24.9 (At risk obesity), 25.0-29.9 (Obese I) and > 30 (Obese II).

Definitions of TB patients:[10]

I. Case definitions:

1. Pulmonary Tuberculosis, Smear-Positive: TB in a patient with at least one smear-positive for acid fast bacilli (AFB) out of the two initial sputum smear examination by direct microscopy.
2. Pulmonary Tuberculosis, 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 is classified as having smear negative pulmonary tuberculosis.
3. Extra Pulmonary Tuberculosis: Tuberculosis in any organ other than lungs (e.g. pleura, lymph nodes, intestine, genitourinary tract, joints and bones, meninges of the brain etc).

II. Type of cases:[10]

1. New: A TB patient who has never taken treatment for TB or has taken anti-TB drugs for less than one month.
2. 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 sputum smear-positive.
4. Transferred in: A TB patient who has been received for treatment in a Tuberculosis Unit, after starting treatment in another TB unit where s/he has been registered.
5. Treatment after default: A patient, who has 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.
6. Treatment failure: Any TB patient who is smear-positive at 5 months or more after initiation of treatment.

Blood glucose estimation:

All participants, who are non diabetic but having symptoms of DM (polydipsia, polyuria, weight loss) were checked for random blood glucose levels. Classification of DM was done using American Diabetic Association criteria as follows:

Table 6: Criteria for the diagnosis of diabetes mellitus[61]

Symptoms of diabetes plus random blood glucose concentration ≥11.1mmol (200 mg/dL) **OR**
Fasting plasma glucose ≥ 7 mmol (126 mg/dL) **OR**
Hemoglobin $A_{1c\geq}$ 6.5% **OR**
2-h plasma glucose ≥11.1mmol (200 mg/dL) during an oral glucose tolerance test

Statistical analysis:

The data was presented in the form of tables and graphs wherever necessary. All characteristics were summarized descriptively. For continuous variables, the summary statistics of mean, standard deviation (SD) were used. For categorical data, the number and percentage were used in the data summaries. Chi-square (χ^2)/ Freeman-Halton Fisher exact test was employed to determine the significance of differences between groups for categorical data. The difference of the means of analysis variables between two independent groups was tested by unpaired t test. If the p-value was < 0.05, then the results were considered to be statistically significant otherwise it was considered as not statistically significant. Data were analyzed using SPSS software v.23.0. and Microsoft office.

RESULTS

Table 7: Distribution of Socio demographic characteristics of study participants (n=215)

Study variable	Number (n)	Percentage (%)
Age (yrs)		
15-25	32	14.9
26-35	58	27.0
36-45	45	20.9
46-55	47	21.9
56-65	26	12.0
>65	7	3.3
Sex		
Male	138	64.2
Female	77	35.8
Place		
Rural	190	88.0
Urban	25	12.0
Marital status		
Married	193	89.8
Unmarried	17	7.9
Widowed	5	2.3
Religion		
Hindu	189	87.9
Muslim	26	12.1
Education		
Illiterate	32	14.9
Primary	117	54.4
Secondary	51	23.7
PUC	14	6.5
Graduate	1	0.5
Type of Family		
Nuclear	187	87.0
Joint	28	13.0
Socioeconomic class		
Upper class	4	1.9
Upper middle class	8	3.7
Middle class	55	25.6
Lower middle class	43	20.0
Lower class	105	48.8

The above table shows that out of 215 study participants, majority (27%) of them belonged to age group of 26-35 yrs followed by 46-55 yrs (21.9%) and 36-45 yrs (20.9%). This shows that most of the study participants were in reproductive age

group. In our study males were predominant i.e. 64.2% (138) and females constituted 35.8% (77). 88% of the tuberculosis patients were from rural background.

89.8% of the study participants were married and only 7.9% were unmarried and there were about 2.3 % widowed participants in the study. 87.9% of study participants belonged to Hindu religion and rest of them i.e. 12.1% belonged to Muslim community.

More than half (54.4%) of the study participants studied up to primary school followed by secondary school (23.7%) and there were 14.9% of illiterates in the study. In this study 87% (187) of the participants belonged to nuclear family while 13% (28) were from the joint family.

In our study 48.8% of the participants belonged to lower class according to modified B G Prasad's classification followed by 25.6% to middle class and 20% to lower middle class.

Table 8: Distribution of Behavioural pattern among study participants (n=215)

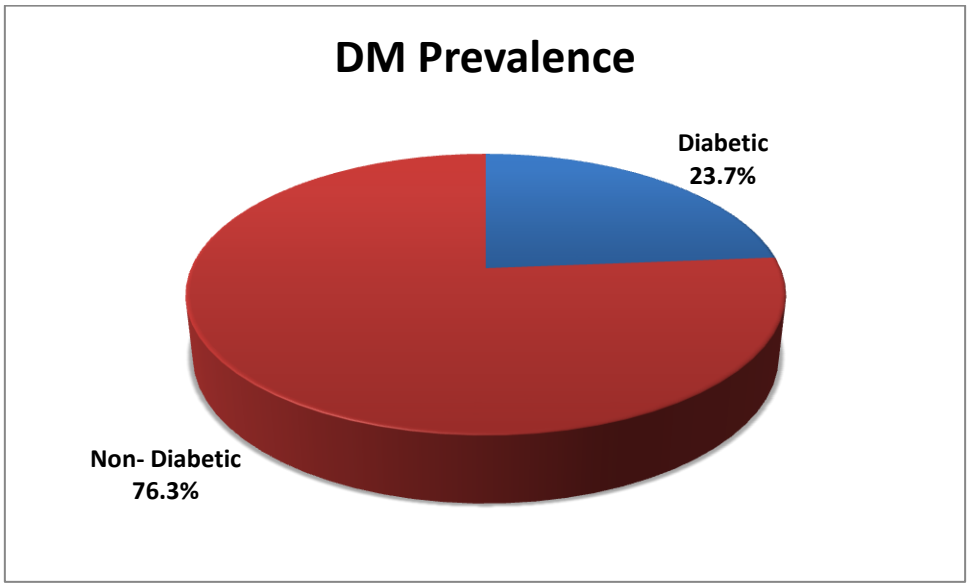
Study variable	Number (n)	Percentage (%)
Food habits		
Vegetarian	122	56.7
Mixed	93	43.3
Smoking		
Current smoker	10	4.7
Ex smoker	56	26.0
Non smoker	149	69.3
Alcohol consumption		
Alcoholic	34	15.8
Non alcoholic	181	84.2
Occupation		
Non government	172	80.0
Government	3	1.4
House wife	30	14.0
Student	10	4.6
Physical activity		
Sedentary	7	3.3
Moderate	205	95.3
Heavy	3	1.4

When looked up on the food habits of the study participants 56.7 % were vegetarians and 43.3% used to consume both vegetarian and non-vegetarian food items. 4.7% of the study participants were current smokers and 26% were ex smokers; however 69.3% were non smokers. Majority (84.2%) of the study participants were non alcoholic and about 15.8% used to consume alcohol. Most (95.3%) of the study participants were engaged in moderate activity followed by 3.3% and 1.4% in sedentary and heavy work respectively.

Table 9: Distribution of Prevalence of DM among TB patients (n=215)

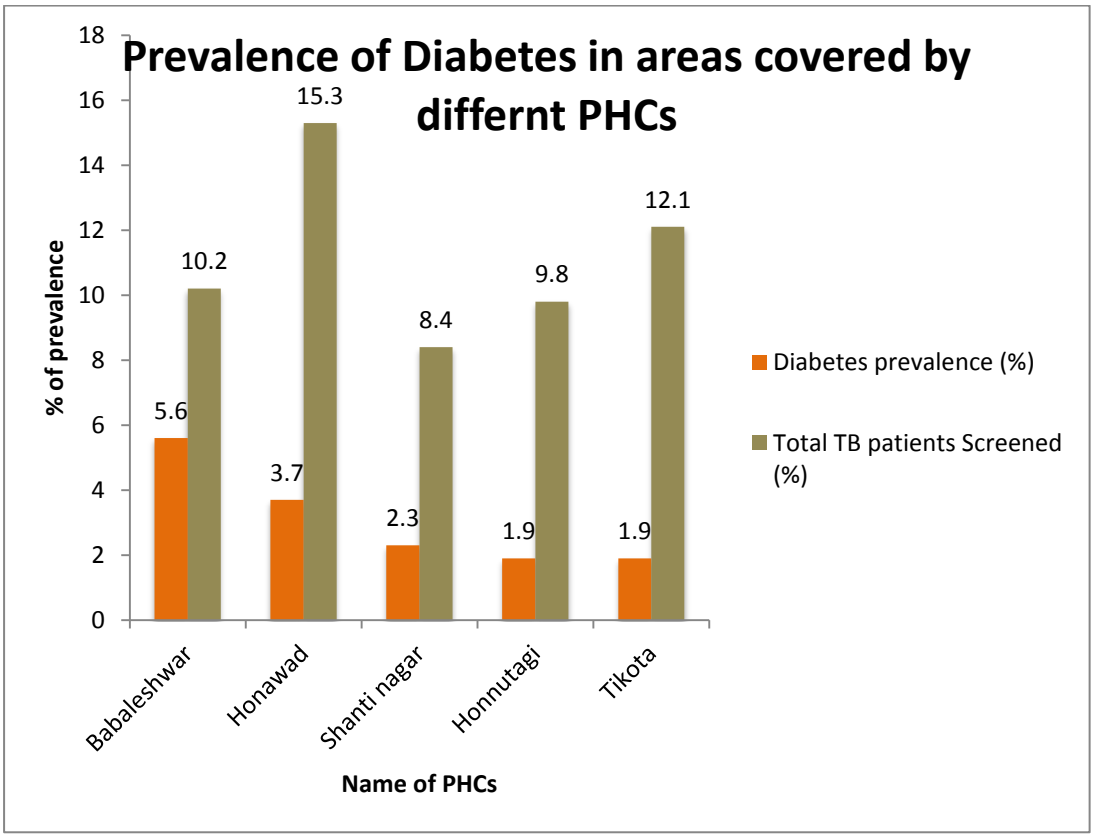
DM Prevalence	Number (n)	Percentage (%)
Diabetic	51	23.7
Non- Diabetic	164	76.3
Total	215	100.0

Figure 2: Distribution of Prevalence of DM among TB patients



Out of 215 study participants the prevalence of diabetes mellitus was 23.7% (51).

Figure 3: Distribution of Prevalence of DM according to PHC (top 5 PHCs)



In our study Honawad PHC area had more participants 15.3% whereas the prevalence of diabetes mellitus was highest in Babaleshwar PHC i.e. 5.6%.

Table 10: Distribution of treatment profile among study participants (n=215)

Study variable	Number (n)	Percentage (%)
Treatment phase		
Continuous phase	159	74.0
Intensive phase	56	26.0
Regularity of Treatment		
Yes	140	65.2
No	75	34.8
Side effects		
Yes	69	32.1
No	146	67.9
Follow up result		
Subjective feeling	190	88.4
Sputum conversion	178	82.8
Weight gain	65	30.2

Out of 215 study participants 74% (159) were in continuation phase of the TB treatment and 26% (56) were in intensive phase. 65.2% patients took the anti TB drugs regularly. In our study about 32.1% (69) of participants have experienced side effects following treatment for tuberculosis. On follow up of these cases majority reported both subjective wellness and sputum conversion.

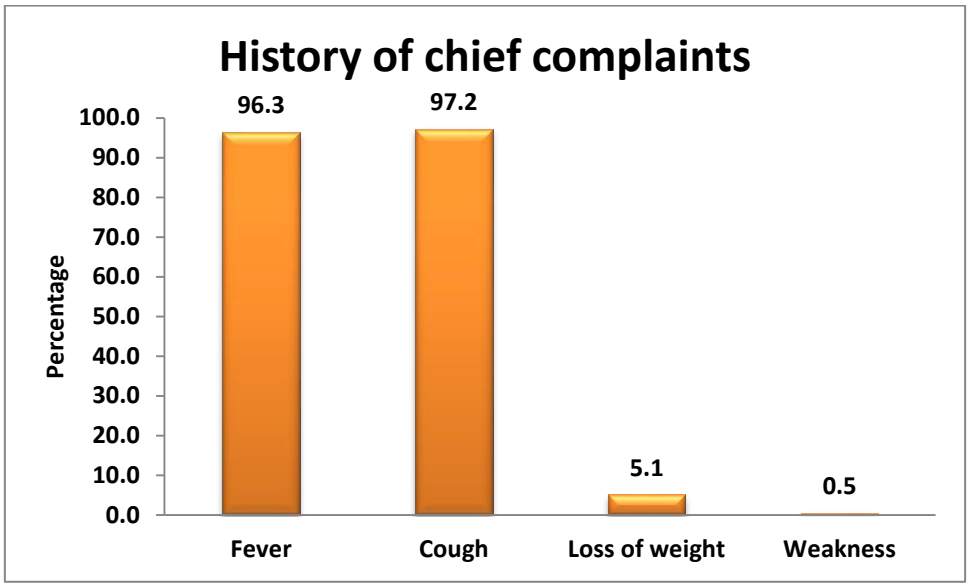
Table 11: Mean age of the study participants according to DM status

	Diabetic		Non- Diabetic		p value
	Mean	SD	Mean	SD	
Age (yrs)	52.1	10.2	37.1	13.0	**<0.001***

Note:*significantly distributed at 5% level of significance

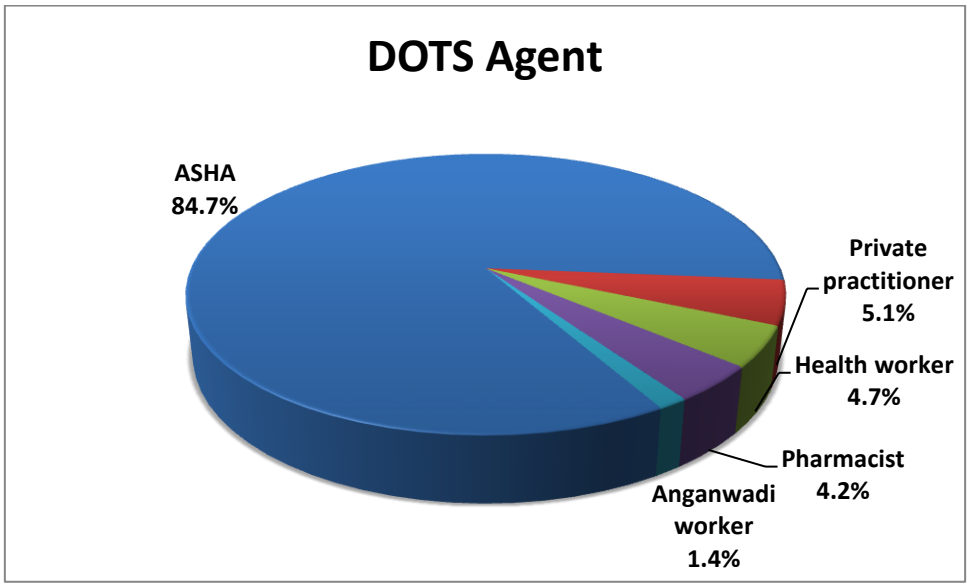
The mean age of DMTB patients was 52±10.2 and found to be statistically significant which indicates increasing age as a risk factor for DM.

Figure 4: Distribution of cases according to History of chief complaints.



The bar graph shows that majority of the cases presented with fever and cough as their chief complaint. (* multiple responses were obtained from TB patients) .

Figure 5: Distribution of cases according to treatment provided by DOTS Agent



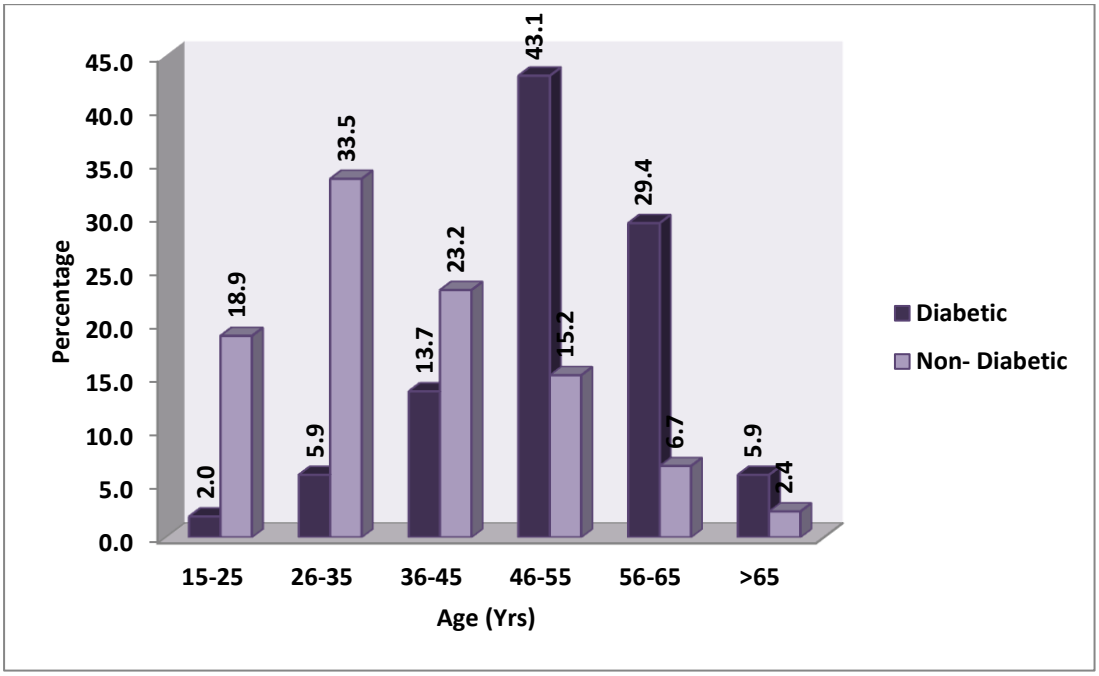
According to our study findings in majority (84.7%) of cases ASHA was the DOTS agent followed by private practitioner 5.1% and health worker 4.7% respectively.

Table 12: Association of Prevalence of DM and Age (n=215)

Age (yrs)	Diabetic		Non- Diabetic		p value
	n	%	n	%	
15-25	1	2.0	31	18.9	**<0.001***
26-35	3	5.9	55	33.5	
36-45	7	13.7	38	23.2	
46-55	22	43.1	25	15.2	
56-65	15	29.4	11	6.8	
>65	3	5.9	4	2.4	
Total	51	100.0	164	100.0	

Note:*significantly distributed at 5% level of significance

Figure 6: Association of Prevalence of DM and Age



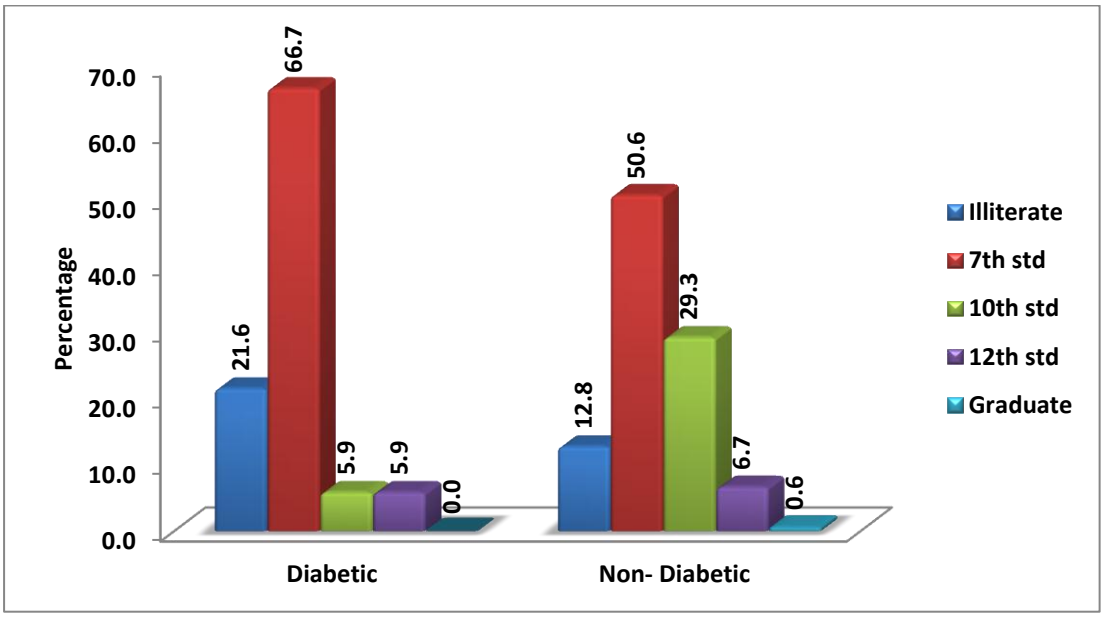
When the prevalence of diabetes mellitus was compared with the age it was found that majority (43.1%) of the diabetics were in the age group of 46-55 years and it was statistically significant with the p value of < 0.001.

Table 14: Association of Prevalence of DM and Educational status (n=215)

Educational status	Diabetic		Non- Diabetic		p value
	n	%	n	%	
Illiterate	11	21.6	21	12.8	**0.01***
Primary	34	66.6	83	50.6	
Secondary	3	5.9	48	29.3	
PUC	3	5.9	11	6.7	
Graduate	0	0.0	1	0.6	
Total	51	100.0	164	100.0	

Note:*significantly distributed at 5% level of significance

Figure 7: Association of Prevalence of DM and Educational status



On comparing the association between prevalence of diabetes mellitus and educational status, among diabetics most of the study participants 66.7% (34) studied up to primary school and it was statistically significant i.e. illiteracy and primary education was significantly associated.

Table 14: Association of Prevalence of DM and Smoking habits (n=215)

Smoking habits	Diabetic		Non- Diabetic		p value
	n	%	n	%	
Current smoker	2	3.9	8	4.9	**0.049***
Ex smoker	20	39.2	36	22.0	
Non smoker	29	56.9	120	73.1	
Total	51	100.0	164	100.0	

Note:*significantly distributed at 5% level of significance

From the above table it is seen that, the prevalence of DM was high among non smokers (56.9%) and it indicates the negative association in the present study.

Table 15: Association of Prevalence of DM and Alcohol consumption (n=215)

Alcohol consumption	Diabetic		Non- Diabetic		p value
	n	%	n	%	
Alcoholic	15	29.4	19	11.6	**0.002***
Non alcoholic	36	70.6	145	88.4	
Total	51	100.0	164	100.0	

Note:*significantly distributed at 5% level of significance

The prevalence of diabetes mellitus was more in non alcoholics 70.6% (36) and this was found statistically significant. Hence alcohol consumption was not a risk factor in our study.

Table 16: Association of Prevalence of DM and Physical activity (n=215)

Physical activity	Diabetic		Non- Diabetic		p value
	n	%	n	%	
Sedentary	2	3.9	5	3.0	**0.007***
Moderate	46	90.2	159	97.0	
Heavy	3	5.9	0	0.0	
Total	51	100.0	164	100.0	

Note:*significantly distributed at 5% level of significance

The prevalence of DM was high (90.2%) among patients engaged in moderate activity and was found statistically significant.

Table 17: Association of Prevalence of DM and Family H/o DM (n=215)

Family H/o DM	Diabetic		Non- Diabetic		p value
	n	%	n	%	
No	46	90.2	162	98.8	**0.003***
Yes	5	9.8	2	1.2	
Total	51	100.0	164	100.0	

Note:*significantly distributed at 5% level of significance

90.2% of DM prevalence was found among patients not having family history of DM and was statistically significant.

Table 18: Association of Prevalence of DM and BMI (n=215)

BMI	Diabetic		Non- Diabetic		p value
	N	%	N	%	
Underweight	32	62.7	124	75.6	0.11
Normal	19	37.3	38	23.2	
Overweight/obese	0	0.0	2	1.2	
Total	51	100.0	164	100.0	

We found that the prevalence of DM was not significant when compared with the BMI.

Other parameters like sex (p=0.44), religion (p=0.28), occupation (p=0.27), marital status (p=0.14), food pattern (p=0.33), type of family (p=0.11), socioeconomic status (p=0.58), time interval between onset of symptoms and seeking health care (p=0.27) and treatment phase (p=0.79) were tested for association with prevalence of DM but all were not found significant.

DISCUSSION:

The present study was conducted to estimate the prevalence of DM and to assess the risk factors of DM among TB patients registered under RNTCP in Vijayapura Tuberculosis Unit.

Socio-demographic profile of the participants:

Age group:

In our study it was found that majority of the tuberculosis patients were in the age group of 26-35 years (27%). Most of our participants were in the reproductive age group. Similar results were found in a study done by Damtew E *et al* [24] in Addis Ababa Ethiopia where majority of the patients were 25- 44 years of age.

Another study done by Balakrishnan S *et al* [14] in Kerala revealed that most of the patients were 45-54 years of age. Few other studies done by J Kishan *et al* [56] in Patiala Punjab and Dutt N *et al* [17] in Ahemdabad reported 40-60 of year's age group as most commonly involved.

This difference in age group may be due to different location of the study and study design setting.

The mean age was found to be 52.1 yrs among diabetics and 37.1 among non diabetics which is similar to a study done by Natarajaboopathy R *et al*[20] in Tamil Nadu where mean age of the DM TB patients was 52.92 yrs and was statistically significant.

Padmalatha P *et al*[18] in Andhra Pradesh showed the mean age as 46.5±10.3 among diabetics and 35.8±11.7 among non diabetics.

Sex:

In the current study 64.2% (138) of the respondents were males and 35.8% (77) were females similar to a study done by Tahir Z *et al* [38] in Pakistan where 69.1 were males and 30.9% were females and another study done by Alisjahbana B *et al* [34] in Indonesia in which 52.4% (238) of the patients were males. The reason is fear and stigma associated with tuberculosis which resulted in under- notification in case of females and also the tendency to seek health care.

Place:

In our study 88 % of the patients were from rural back ground, which in contrast to other studies by Damtew E *et al* [24] in Addis Ababa, Ethiopia in which residence of urban was 70% and a study done by Viswanathan V *et al* [15] in Tamil Nadu which had majority of TB patients, (69.9%) from urban back ground. This difference is due to different study settings.

Education:

In the present study more than half 54.4% (117) tuberculosis patients studied up to primary schooling, 23.7% (51) patients completed high school education and 14.9% (32) patients were illiterates, where it was observed that most of the TB patients had received less schooling, which was consistent with other studies.

A study done by Sarkar M *et al* [44] in Bangladesh reported that 25.1% of the participants had primary schooling, 19.8% had secondary schooling and 40.7% were illiterates. Another study by Tahir Z *et al* [38] in Pakistan has shown 51.6% as illiterates, 34.7% as primary schooling and 10.7% as secondary schooling.

Occupation:

In this study 80% (172) of tuberculosis patients were non government workers, followed by 14% (30) housewife and 4.7% (10) were students which is similar to a study done by Viswanathan V *et al* [15] in Tamil Nadu where, 53.9% were unskilled, 17.2% were housewife and 3.3% were students and another cross sectional study done by Kibirige D *et al* [43] in Uganda showed that majority (56.5%) were unskilled workers and self employed were 13.1%.

Marital status:

Our results revealed that majority of the study participants 89.8% (193) were married followed by 7.9% (17) unmarried and 2.3% (5) widowed. This finding was consistent with other studies like Damtew E *et al* [24] in Ethiopia said majority that is 59.2% were married, 36.7% were unmarried and 1.7% was widowed.

Smoking status:

In our study 4.7% of participants were current smokers and 69.3% were non smokers which are in line with a study done by Damtew E *et al* [24] in Ethiopia which revealed 15% as smokers and 85% as non smokers.

But another study done by Ekeke N *et al* [41] in Nigeria showed 4.8% as non smokers and 95.2% as current smokers. This variation may be due to change in the social scenario.

Alcohol consumption:

In this study majority (84.2%) of the TB patients were non alcoholic and about 15.8% used to consume alcohol similar to a study by Viswanathan V *et al* [15] in Tamil Nadu in which 38.9% were non alcoholic and 1.6% were alcoholic.

But another study by Damtew E *et al* [24] in Ethiopia had no much difference in alcohol consumption i.e. 51.7% as non alcoholic and 48.3% as alcoholic which may be due to different socio cultural factors.

Physical activity:

Most (95.3%) of the participants of our study were engaged in moderate activity followed by 3.3% in sedentary work and 1.4% in heavy work respectively.

A study by Ekeke N *et al* [41] in Nigeria reported that 49.8% as sedentary workers, 32.9% as moderate workers and 17.3% as heavy workers.

Socioeconomic class:

In our study 48.8% of the participants belonged to lower class, 25.6% to middle class and 20% to lower middle class according to modified B G Prasad's classification. Our findings are similar to a study done by Agarwal AK *et al* [62] in Madhya Pradesh in which 37.8% belonged to lower class and 15.7% belonged to lower middle class.

The criteria used to classify socioeconomic status were different but there is similarity in terms of currency used.

History of chief complaints:

Our study reported that 96.3% (207) of tuberculosis patients presented with fever and 97.2% (209) with cough as their chief complaint which is consistent with a study done by Babu RV *et al* [57] in Pondicherry where 95.5% of tuberculosis patients had fever and 100% of them had cough as their predominant symptom.

But studies done by Jabbar A *et al* [35] in Pakistan showed that 72% with fever and 66% with cough as their chief complaint. Another study by Amin S *et al* [39] in Pakistan revealed 75% with fever and 56% with cough as their chief complaint.

This variation may be due to different socio demographic factors.

Symptoms of diabetes mellitus:

Current study showed that 89.8% (193) of tuberculosis patients didn't have symptoms suggestive of DM while only 10.2% (22) had so which is similar to a study by Damtew E *et al* [24] in Ethiopia in which 97.5% of the patients had no symptoms and 2.5% had symptoms suggestive of DM. This may due to the fact that active TB is a triggering factor which will precipitate overt diabetes.

Facility type:

92% of tuberculosis patients in our study consulted a government hospital when they had symptoms while only 8% of them to a private hospital which is similar to a study done by Ekeke N *et al* [41] in Nigeria in which 62.8% preferred the public hospital and 37.2% to a private one.

Family history of DM:

Present study showed that only 3.3% (7) of study participants had family history of DM and 96.7% (208) had no family history which is in contrast to a study done by Workneh MH *et al* [25] in Ethiopia where 94 .8% of tuberculosis patients reported the family history of DM. The history of DM among one or more family members is significantly high among the DMTB patients (54.9%) in the studies by Viswanathan V *et al*[15]. This may be due to difference in the genetic factors.

Prevalence of DM:

The prevalence of DM among TB patients in our study was 23.7% which is in consistent with report of other studies[63] done in Karnataka State in 2011 where the prevalence was 32%, in Kerala State 44% (2012) and Tamil Nadu State, India 25% (2012).

Other studies like an institutional based cross sectional study done by Padmalatha P *et al* [18] in Andhra Pradesh showed the prevalence of DM as 30.6%. A facility based cross sectional study done by Raghuraman S *et al* [22] in Pondicherry (2017) reported 29% as DM prevalence.

In contrast to the above findings, another study done in Nigeria by Oliyanka AO *et al* [37] found the prevalence to be 5.7% which could be attributed to difference in demographic characteristics.

We employed American Diabetic Association (ADA) criteria to assess the diabetes mellitus and studied tuberculosis patients registered under RNTCP. Though the results were found to be consistent with those reported by other authors direct comparisons are not valid for the reasons detailed above and also relate to different criteria used by researchers over time to diagnose both conditions, non representativeness of patients studied both in terms of number and selection criteria and different settings. A well planned large scale observational study or meta-analysis has the potential to settle the issue.

DM and Age:

In our study 43.1% of diabetes mellitus prevalence was found among tuberculosis patients aged between 46-55 years of age which is different to a study

done by Kattarath MD *et al* [53] in Pariyaram Kerala where it was > 61 years in both the groups and a study by Ekeke N *et al* [41] in Nigeria where 16.9% of DM prevalence was found among 56-65 years of age.

DM and Sex:

Our study has reported that majority (68.6%) of the prevalence among males similar to a study by Agarwal AK *et al* [62] in Madhya Pradesh (77%) and other study by Viswanathan V *et al*[15]. The higher prevalence of DM among males might be due to other risk factors such as smoking tobacco and alcohol consumption, which effect both TB and DM. The other reason could be the younger age of females since increasing age emerged as a significant risk factor for diabetes.

DM and Education:

In our study the prevalence of DM was high among those who had less education (21.6% illiterates and 66.7% primary school) which is similar to a study by Kornfeld H *et al* [64] in South India where 51.4% of diabetic patients were illiterates. This is due to the reason that less educated patients don't have awareness about the diseases.

DM and Socioeconomic class:

The prevalence of DM (25 out of 51 cases) was high among lower socioeconomic class in our study, similar to a study by Sangral R *et al* [13] in Jammu in which approximately two-third of patients belonged to lower & lower middle class families.

The reasons for increased prevalence are lower immunity, malnutrition, poverty, inaccessibility to health care facilities, ignorance and lack of awareness about the disease.

Another study done by Viswanathan V *et al* [15] in Tamil Nadu showed no significant association with income status, this is due to different study settings as they had more number of TB patients from urban area.

DM related to Smoking habits:

A study done by Tiwari VK *et al* [21] in Delhi has reported no significant association between the prevalence of DM and smoking which is similar to our study, but it is in contrast to a study done by Tahir Z *et al* [38] in Lahore Pakistan where smoking positively was associated with DM.

DM related to Alcohol consumption:

In a study done by Mkhontfo MM *et al* [33] in the state of Florida USA there was significant association between DM and alcohol consumption and a report from Portuguese has showed no significant association which is similar to our study.

DM and BMI.

We also found no association of BMI with TB and coexistent DM in our study. The difference in conclusions might have to do with socioeconomic differentials in patients studied in different setting.

SUMMARY

The present study titled – "**A study to determine the prevalence of diabetes mellitus among newly detected sputum positive pulmonary tuberculosis patients in Vijayapura taluk, Vijayapura district**" was undertaken to know the prevalence of DM among TB patients and to assess the risk factors.

This cross sectional study was carried out in Vijayapura TU comprising of 14 PHCs, 4 UPHCs and 2 medical colleges. A total of 215 TB patients, were included in the study and the duration of the study was for one year from 1st January 2016 to 1st January 2016.

In the current study majority (27%) belonged to 26-35 years of age and 64.2% were males. Most (89.8%) of them were married and 87.9% were Hindus by religion. A large number (54.4%) of TB patients studied up to primary school. About, 48.8% of the patients belong to Class V socioeconomic status as per modified B G Prasad's classification and 87% were living in a nuclear family. Mean age of the study participants was 52 years among diabetics and 37 years among non diabetics.

As many as 80% TB patients were non government employees and 14% were house-wives. Half (56.7%) of the participants were vegetarians, 69.3% were non smokers and 84.2 % were non alcoholics. Most (95.3%) of the TB patients were engaged in moderate work.

Majority of the TB patients presented with fever and cough as their chief complaints (96.3% and 97.2% respectively). 85.1% of them sought health care facility within 7 days of onset of their symptoms.

About 74% of the TB patients were in continuation phase of treatment regimen. ASHA was the DOTS agent in 84.7% of TB patients. 65.2% of them have reported that they are taking the drugs regularly and most (67.9%) of them had side effects. 88.4% of TB patients had feeling of wellness after starting the anti TB treatment. Majority (96.7%) of the study participants had no family H/o diabetes mellitus. Most of the study participants 72.6% were underweight and the mean BMI $(kg/m)^2$ was 17.7 among diabetics and 16.8 among non diabetics.

In our study the prevalence of DM among TB patients was found to be 23.7% (2.8% known and 97.8% new cases). Among all the PHCs the prevalence was high in Babaleshwar i.e. 5.6%.

Various socio demographic variables had influence over the prevalence of DM. Significant associations were found between age (p=0.001), educational status (p=0.01), smoking habits (p=0.049), alcohol consumption (p=0.002), physical activity (p=0.007), presence of symptoms of DM (0.001) and family H/o DM (0.003).

Nevertheless, there were no statistical significant associations observed between sex, religion, occupation, marital status, food pattern, type of family, socioeconomic status, time interval in seeking health care, treatment phase, BMI.

Routine screening for DM in all TB patients is warranted because of the increasing prevalence of DM among TB patients. This may help in early diagnosis of DM as well as to reduce the possible complication of the disease by proper management, which in turn will also help in successful outcome of TB treatment regimen.

CONCLUSION

The present study showed that, the prevalence of DM among TB patients registered under RNTCP in Vijayapura Tuberculosis Unit was 23.7% (2.8% known and 97.8% new cases). The DMTB patients were more between 46-55 years of age, majority of them studied up to primary school and belonged to lower socioeconomic status. Most of them were underweight due to the DMTB comorbidity. Various factors like age, educational status; smoking habits, alcohol consumption, physical activity, and family H/o DM have influenced the prevalence.

LIMITATIONS

- Few of the variables analyzed were based on the information obtained by the study participants. Hence an element of recall bias and masking of data could be present in the study.
- TB patients registered under RNTCP were included in the study; patients taking treatment in private hospitals were not included.
- Among all the TB patients only new sputum positive pulmonary TB patients were included which may be the limitation.
- In the present study few risk factors of DM were studied. All other risk factors could not be studied because of lack of resources.

RECOMMENDATIONS

In view of the present study findings the following recommendations are made:

- The prevalence of DM among TB patients was 23.7% which is quite high, so screening of all TB patients should be done just like HIV screening. This screening will help in early diagnosis and proper management of the disease.
- Primordial prevention can play an important role in preventing the occurrence of DM. Health education regarding the risk factors and symptoms of DM should be given to high risk groups. These activities will also increase the prevention.
- For DMTB patients, regular blood glucose estimation and treatment should be given in DOTS centres along with anti-TB drugs.

References:

1. Revised National TB Control Programme Technical and Operational Guidelines for Tuberculosis Control in India 2016.India. p 269.
2. Park K. Epidemiology of Communicable Diseases. In: Textbook of Preventive and Social Medicine. 24th edition. Jabalpur, India: M/s Banarsidas Bhanot Publishers; 2017.p.185-216.
3. History of tuberculosis [Internet] 2017[cited on Oct 14 2017] [updated 2017 Oct 12] Available from: https://en.wikipedia.org/wiki/History_of_tuberculosis
4. History of diabetes mellitus [Internet] 2017[cited on Oct 14 2017] [updated 2017 Sep 2] Available from: https://en.wikipedia.org/wiki/History_of_diabetes
5. Samal J. Screening of Tuberculosis patients for possible diabetes mellitus in India: a systematic review. Egyptian Journal of Bronchology.2017:1-5.
6. Epidemiology of diabetes mellitus [Internet] 2017 [cited on Oct 14 2017] [updated 2017 Oct 4] Available from:https://en.wikipedia.org/wiki/ Epidemiology_of_diabetes_mellitus
7. WHO. Global Tuberculosis Report 2016.Executive summary.
8. Epidemiology of tuberculosis [Internet] 2017 [cited on Oct 14 2017] [updated 2017 Sep 22] Available from: https://en.wikipedia.org/wiki/ Epidemiology_of_tuberculosis
9. Park K. National Health Programmes. In: Textbook of Preventive and Social Medicine. 24th edition. Jabalpur, India: M/s Banarsidas Bhanot Publishers; 2017.p.445-451.

10. Kishore J. Revised National Tuberculosis Control Program (RNTCP): DOTS Strategy. In: J. Kishore's National Health Programs of India. 12th edition. New Delhi, India: Century Publications; 2016.p.269.
11. Ramamurti T. Pathology of Mycobacterial Infection in Diabetes. Int. J. Diab. Dev. Countries.1999;19:56-60.
12. Niazi AK, Kalra S. Diabetes and tuberculosis: a review of the role of optimal glycemic control. Journal of Diabetes & Metabolic Disorders.2012;11(28):1-4.
13. Sangral R, Kumar D, Bhatia AS. Diabetes Mellitus Among Tuberculosis Patients in A Rural Population of Jammu - A Community Based Observational Study.2012 Dec;14 (4):177-180.
14. Balakrishnan S, Vijayan S, Nair S, Subramoniapillai J, Mrithyunjayan S. High Diabetes Prevalence among Tuberculosis Cases in Kerala, India. PLoS ONE.2012 7(10):1-7.
15. Viswanathan V, Kumpatla S, Aravindalochanan V, Rajan R, Chinnasamy C, Srinivasan R *et al*. Prevalence of Diabetes and Pre-Diabetes and Associated Risk Factors among Tuberculosis Patients in India.PLoS ONE.2012;7(7):1-9.
16. Khanna A, Lohya S, Sharath BN, Harries AD. Characteristics and treatment response in patients with tuberculosis and diabetes mellitus in New Delhi, India. PHA.2013 Nov;3:48-50.
17. Dutt N, Gupta A. A Study On Diabetes Mellitus Among Cases Of Pulmonary Tuberculosis In A Tertiary Care Hospital, Ahmedabad.National Journal Of Medical Research.2014 Dec;4(4):349-353.
18. Padmalatha P, Hema K. Study on prevalence of Diabetes Mellitus in Tuberculosis patients attending a tertiary care hospital in Guntur, Andhra Pradesh. IJBAMR.2014 Dec;4(1):494-498.

19. Mansuri S, Chaudhari A, Singh S, Malek R, Viradiya R. Prevalence of Diabetes among Tuberculosis Patients at Urban Health Centre, Ahmedabad. Int J Sci Stud 2015;3(4):115-118.
20. Natarajaboopathy R, Jayanthi NN. A study on prevalence of diabetes and pre-diabetes in a newly diagnosed tuberculosis patients. J. Evolution Med. Dent. Sci. 2016;5(99):7231-7233.
21. Tiwari VK, Verma P, Raj S. Factors associated with Diabetes Mellitus among Tuberculosis Patients attending Tertiary Care Hospital in Delhi, India.Indian J Comm Health.2016;28(4):369-373.
22. Raghuraman S, Vasudevan KP, Govindarajan S, Chinnakali P, Panigrahi KC. Prevalence of diabetes mellitus among tuberculosis patients in Urban Puducherry. North Am J Med Sci.2014;6:30-34.
23. Mahishale V, Avuthu S,Patil B,Lolly M, Eti A, Khan S. Effect of Poor Glycemic Control in Newly Diagnosed Patients with Smear-Positive Pulmonary Tuberculosis and Type-2 Diabetes Mellitus. Iran J Med Sci March. 2017; 42(2):144-151.
24. Damtew E, Ali I, Meressa D. Prevalence of Diabetes Mellitus among Active Pulmonary Tuberculosis Patients at St. Peter Specialized Hospital, Addis Ababa, Ethiopia. World J. Med. Sci.2014; 11(3):389-396.
25. Workneh MH, Bjune GA, Yimer SA. Prevalence and Associated Factors of Diabetes Mellitus among Tuberculosis Patients in South Eastern Amhara Region, Ethiopia: A Cross Sectional Study.PLoSONE.2016;11(1):1-15.
26. Dobler CC, Flack JR, Marks GB. Risk of tuberculosis among people with diabetes mellitus: An Australian nationwide cohort study. BMJ Open 2012; 2:1-5.

27. Al-Adhami SB, Al-Mgoter BS. Pulmonary Tuberculosis in Patients with Diabetes Mellitus. Iraqi J. Comm. Med.2008 Jan;21(1):47-54.
28. Umakanth M, Rishikesavan S. Prevalence of diabetes mellitus among tuberculosis patient in Batticaloa district, Sri Lanka. Int J Med Res:2017 Mar;2(2):21-23.
29. Li L *et al*. Screening of patients with tuberculosis for diabetes mellitus in China. Trop Med Int Health.2012 Oct;17(10):1294–1301.
30. Faurholt-Jepsen *et al*. The role of diabetes co-morbidity for tuberculosis treatment outcomes: a prospective cohort study from Mwanza, Tanzania. BMC Infectious Diseases.2012;12(165):1-8.
31. Zheng C, Hu M, Gao F. Diabetes and pulmonary tuberculosis: a global overview with special focus on the situation in Asian countries with high TBDM burden, Global Health Action.2017; 10(1):1-11.
32. Chaudhry LA, Essa EB, Solaiman SA, Al-Sindi K.Prevalence of diabetes type-2 and pulmonary tuberculosis among Filipino and treatment outcomes: A surveillance study in the Eastern Saudi Arabia.Int J Mycobact.2012 Mar: 106-109.
33. Mkhontfo, Mandzisi Mbongeni. "An Examination of The Distribution of Diabetes Mellitus Among TB Patients with Pulmonary Tuberculosis and Drug Resistant Tuberculosis In The State Of Florida, USA." (2016) [cited on Sep 20 2017]. Graduate Theses and Dissertations. Available from: http://scholarcommons.usf.edu/etd/6325
34. Alisjahbana B *et al*. Diabetes mellitus is strongly associated with tuberculosis in Indonesia. INT J TUBERC LUNG DIS.2006 Jan;10(6):696–700.

35. Jabbar A, Hussain SF, Khan AA. Clinical characteristics of pulmonary tuberculosis in adult Pakistani patients with co-existing diabetes mellitus. East Mediterranean Health J.2006;12(5):522-527.
36. Tahir NB, Uddin QT, Munir SS, Waheed A, Waheed S, Daud HM. Prevalence of Diabetes Mellitus in tuberculosis patients at DOTS regional centre KMU-IMS teaching Hospital Kohat.Eur Acad Res.2014 Oct;2(7):9948-9959.
37. Olayinka AO, Anthonia O, Yetunde K. Prevalence of diabetes mellitus in persons with tuberculosis in a tertiary health centre in Lagos, Nigeria. Indian J Endocr Metab. 2013;17:486-489.
38. Tahir Z, Ahmad M, Akhtar AM, Yaqub T, Mushtaq MH, Javed H. Diabetes mellitus among tuberculosis patients: a cross sectional study from Pakistan. Afri Health Sci 2016;16(3): 671-676.
39. Amin S,Khattak MI,Shabbier G,Wazir MN. Frequency Of Pulmonary Tuberculosis In Patients With Diabetes Mellitus.Gomal J of Med Sci.2011 Dec;9(2):163-165.
40. Noureen. Diabetes Mellitus and Associated Risk Factors among Tuberculosis Patients in Rawalpindi, Pakistan. Anatomy Physiol Biochem Int J. 2017;1(4): 1-6.
41. Ekeke N *et al*. Screening for diabetes mellitus among tuberculosis patients in Southern Nigeria: a multi-centre implementation study under programme settings. Sci. Rep.2017 Mar;7:1-8.
42. Usmani RA, Nasir MI, Wazir S, Pervaiz Z, Zahra T, Akhtar M. Diabetes Mellitus Among Tuberculosis Patients In A Tertiary Care Hospital Of Lahore. J Ayub Med Coll Abbottabad.2014;26(1):61–63.

43. Kibirige D, Ssekitoleko R, Mutebi E, Worodria W. Overt diabetes mellitus among newly diagnosed Ugandan tuberculosis patients : a cross sectional study.BMC Infectious Diseases.2013;13(122):1-8.
44. Sarker M, Barua M, Guerra F,Saha A, Aftab A, Latif AHMM, *et al*. Double Trouble: Prevalence and Factors Associated with Tuberculosis and Diabetes Comorbidity in Bangladesh.PLoS ONE.2016 Oct;11(10):1-15.
45. Reis-Santos B *et al*.Socio-Demographic and Clinical Differences in Subjects with Tuberculosis with and without Diabetes Mellitus in Brazil – A Multivariate Analysis. PLoS ONE.2013;8(4):1-6.
46. Gil-Santana L *et al*. Diabetes Is Associated with Worse Clinical Presentation in Tuberculosis Patients from Brazil: A Retrospective Cohort Study. PLoS ONE.2016 Jan;11(1):1-13.
47. Leegaard A *et al*. Diabetes, Glycemic Control, and Risk of Tuberculosis. Epi Health Services Res.2011 Dec;34(12):2530-2535.
48. Mukhtar F, Butt ZA. Cohort profile: the diabetes tuberculosis treatment outcome (DITTO) study in Pakistan. BMJ Open. 2016 Nov;6:1-8.
49. Gnanasan S *et al.* Convergence of tuberculosis and diabetes mellitus: time to individualise pharmaceutical care. Int J Clin Pharm.2011;33:44–52.
50. Ponce-de-Leon A *et al*. Tuberculosis and Diabetes in Southern Mexico. Health & Medical Collection.2004 Jul;27(7):1584-1590.
51. Kang YA *et al*. Impact of Diabetes on Treatment Outcomes and Long-Term Survival in Multidrug-Resistant Tuberculosis. Respiration. 2013;86:472–478.
52. Perez-Navarro LM, Fuentes Dominguez FJ, Cuevas RZ. Type 2 diabetes mellitus and its influence in the development of multidrug resistance

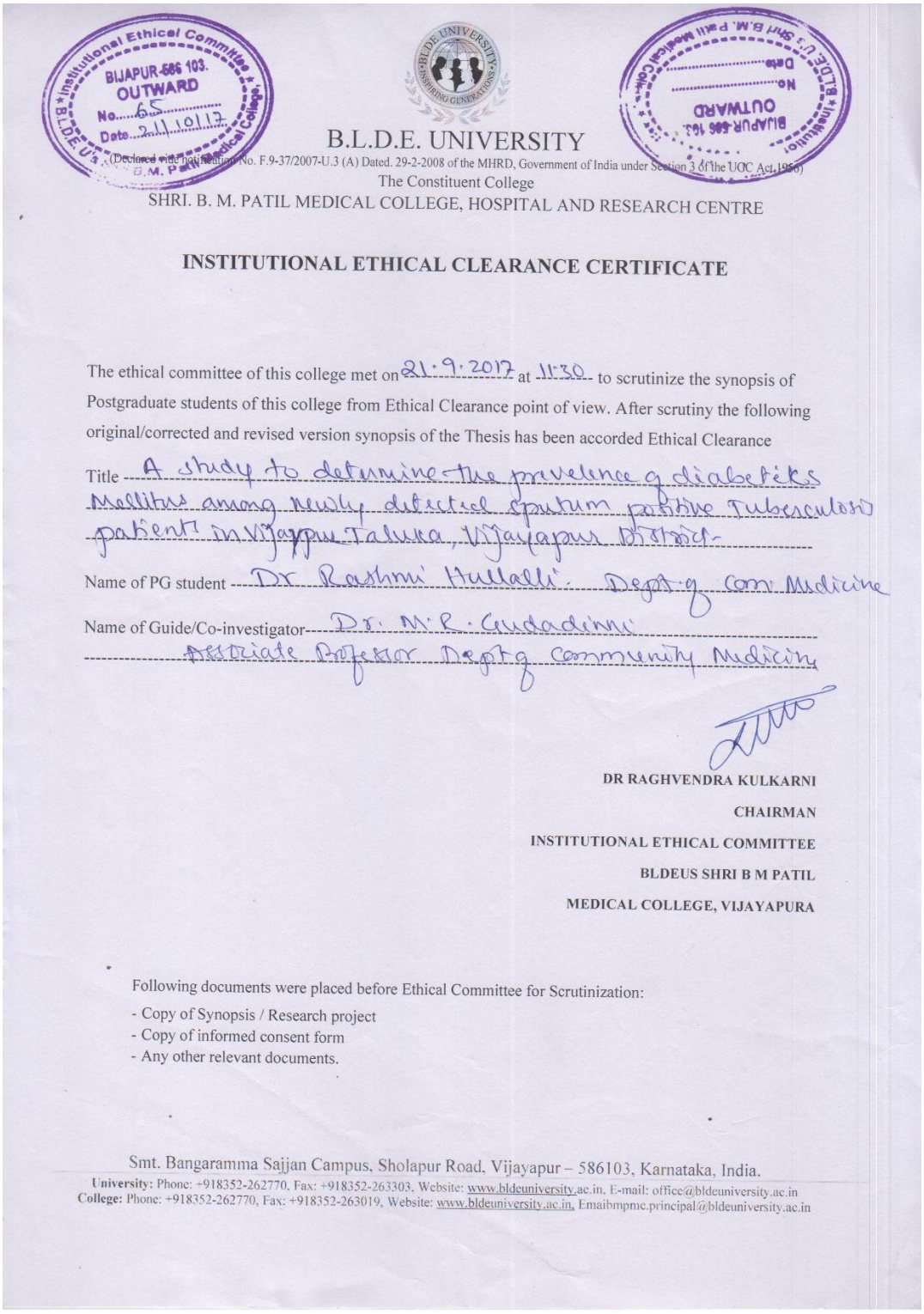
tuberculosis in patients from south eastern Mexico. Journal of Diabetes and Its Complications.2015;29 :77–82.

53. Chiang CY *et al*. The Influence of Diabetes, Glycemic Control, and Diabetes-Related Comorbidities on Pulmonary Tuberculosis. PLoS ONE.2015;10(3): 1-15.
54. A Kumar *et al*. Screening of patients with diabetes mellitus for tuberculosis in India.Trop. Med. Int. Health.2013;18(5):646-54.
55. Kottarath MD, Mavila R, Achuthan V, Nair S. Prevalence of diabetes mellitus in tuberculosis patients-a hospital based study. Int J Res Med Sci.2015 Oct;3(10):2810-2814.
56. J Kishan, K Garg. Tuberculosis And Diabetes Mellitus: A Case Series of 100 Patients. SAARC J. TUBER. LUNG DIS. HIV/AIDS.2010;7(2):34-38.
57. Babu RV, Manju R, Kumar SV, Das AK. A Comparative Study of Diabetes Mellitus in Pulmonary Tuberculosis Patients.World J. Med. Sci.2013;9(2): 93-96.
58. Kishore J, Grewal I. Practical and viva community medicine. 3rd edition. Century publications. New Delhi. 2014; 70-72.
59. Shaikh Z, Pathak R. Revised Kuppuswamy and B G Prasad socio-economic scales for 2016. Int J Community Med Public Health 2017;4:997-999.
60. A training manual for height, weight and BMI assessment. Developed by BMI task force [Internet] 2010 [cited 2015 September 20].Available from: www.achi.net>BMIContent>Documents.
61. Kasper DL, Hauser SL, Jameson JL, Fauci AS, Longo DL, Loscalzo J. Harrisons principles of internal medicine.2015; 19(2):2401.

62. Agarwal AK, Gupta G, Marskole P, Agarwal A. A study of the patients suffering from tuberculosis and tuberculosis-diabetes comorbidity in Revised National Tuberculosis Control Program Centers of Northern Madhya Pradesh, India. Indian J Endocr Metab.2017;21(4):570-576.
63. The Looming Co-Epidemic of Tb-Diabetes: A Call to Action. Available from: https://www.theunion.org/what-we-do/publications/technical/english/EMBARGOED-DMTB-REPORT-Oct-22.pdf
64. Kornfeld H. High Prevalence and Heterogeneity of Diabetes in Patients with TB in South India. Chest.2016; 149(6):1501-1508.

ANNEXURES

ETHICAL CLEARANCE CERTIFICATE



B.L.D.E. UNIVERSITY

(Declared vide notification No. F.9-37/2007-U.3 (A) Dated. 29-2-2008 of the MHRD, Government of India under Section 3 of The UGC Act,1956)

The Constituent College

SHRI. B. M. PATIL MEDICAL COLLEGE, HOSPITAL AND RESEARCH CENTRE

INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The ethical committee of this college met on 21.9.2017 at 11:30 to scrutinize the synopsis of Postgraduate students of this college from Ethical Clearance point of view. After scrutiny the following original/corrected and revised version synopsis of the Thesis has been accorded Ethical Clearance

Title A study to determine the prevalence of diabetics Mellitus among newly detected Sputum positive Tuberculosis patient in Vijayapur Taluka, Vijayapura District.

Name of PG student Dr Rashmi Hullalli. Deptt of Com Medicine

Name of Guide/Co-investigator Dr. M.R. Gudadinni

Associate Professor Deptt of Community Medicine

DR RAGHVENDRA KULKARNI
CHAIRMAN
INSTITUTIONAL ETHICAL COMMITTEE
BLDEUS SHRI B M PATIL
MEDICAL COLLEGE, VIJAYAPURA

Following documents were placed before Ethical Committee for Scrutinization:

- Copy of Synopsis / Research project
- Copy of informed consent form
- Any other relevant documents.

Smt. Bangaramma Sajjan Campus, Sholapur Road, Vijayapur – 586103, Karnataka, India.
University: Phone: +918352-262770, Fax: +918352-263303, Website: www.bldeuniversity.ac.in, E-mail: office@bldeuniversity.ac.in
College: Phone: +918352-262770, Fax: +918352-263019, Website: www.bldeuniversity.ac.in, Emaibmpmc.principal@bldeuniversity.ac.in

INFORMED CONSENT FORM

TITLE OF TOPIC : **A Study to determine the prevalence of Diabetes Mellitus among Newly Detected Sputum Positive Tuberculosis patients in Vijayapura taluk Vijayapur district.**

GUIDE : **DR. M. R GUDADINNI**

PG STUDENT : **DR RASHMI HULLALLI**

PURPOSE OF RESEARCH:

I have been informed that this study will help to known the prevalence of diabetes mellitus among tuberculosis patients in Vijayapura taluk. The study is intended to interview the patients and to carry out blood and urine investigations as and when necessary.

PROCEDURE:

I understand that this is a field based programme. In this procedure I will be asked a series of questions by the researcher regarding the topic and blood and urine investigations will be carried out when necessary.

RISK AND DISCOMFORTS:

I understand that I may experience some discomfort during this procedure. This is mainly result of conditions and the procedures of this study are not expected to exaggerate these feelings which are associated with the usual course of study.

BENEFITS:

I understand that my participation in the study as one of the study subjects will help the researcher to analyse the prevalence of diabetes mellitus among tuberculosis patients in Vijayapura taluk.

CONFIDENTIALITY:

Your answers are kept secret. Your name and contact information will never be identified to anyone outside the study.

REQUEST FOR MORE INFORMATION:

I understand that I may ask more questions about the study at any time to Dr. Rashmi Hullalli at the department of community medicine to answer my questions or concerns. I understand that I will be informed of any significant new findings discovered during the course of the study, which might influence my continued participation. A copy of this consent form will be given to me to keep for careful reading.

REFUSAL OR WITHDRAWAL OF PARTICIPATION:

I understand that my participation is voluntary and that I may refuse to participate or may withdraw consent and discontinue participation in the study at any time without prejudice. I also understand that Dr. Rashmi Hullalli may terminate my participation in the study at any time after she has explained the reasons for doing so.

_____ _____

(Guide / Principle Investigator) (Date)

_____ _____

(Investigator) (Date)

STUDY SUBJECT CONSENT STATEMENT:

I confirm that Dr. Rashmi Hullalli has explained to me the purpose of research, the study procedure that I will undergo & the possible discomfort as well as benefits that I may experience in my own language. I have been explained all the above in detail in my language and understand the same.

Therefore, I agree to give consent to participate as a subject in this research project.

_____ _____

(Participant signature) Date:

_____ _____

(Witness signature) Date:

PROFORMA

GENERAL INFORMATION

a) Name-

B) Age- c) Sex- Male/Female d) Religion-

E) Education f) Occupation-

g) Marital Status-

H) Address

i) Food habits- veg/non veg/mixed

j) Smoking status- Current smokers/Ex smokers/ Non smokers/Beedi/Cigarettes

k) Alcohol- Alcoholic / Non alcoholic

l) Physical activity- Sedentary/Moderate/Heavy

m) Type of Family- nuclear/joint/three generation.

n) Number of Family Members-

Children: 1) >5 years

2) 5-18 years

Adult:

o) Annual Income- Per Capita Income-

p) Socio-Economic Class (Mod B G Prasad classification)

q) History:-

1) History of chief complaints-
2) Source of health care delivery- private/government
3) Date of registration at DTC-

4) Time interval between i) onset of symptoms and seeking health care advice
ii) onset of symptoms and registration at DTC

5) When you are diagnosed with tuberculosis?
6) Are you in Intensive phase/Continuation phase?
7) Are you taking treatment regularly? Yes/No
8) Who is the DOT agent?
9) Are there any problems in receiving the treatment?
   i. non availability of drugs
   ii. side effects
   iii. no relief
   iv. difficulty in procuring (time factor)

10) Is there any improvement?
   i. Subjective feeling
   ii. Sputum conversion
   iii. Weight gain
   iv. Increased appetite
11) Do you have the following symptoms? Polydypsia/Polyphagia/Unexplained weight loss/Hyperphagia
12) Have you checked your blood sugar in the last 12 months? Yes/No

13). Are you a known case of DM? Yes/No

   i. If yes - since when?
   ii. Who has diagnosed?

14). Name the preventive and control measures adopted ------

i) Antidiabetic drugs only

ii) Diet modification only

iii) Drugs and diet

iv) Diet and exercise

v) Drugs, diet and exercise

15). Name the antidiabetic drugs you are taking

i. Insulin
ii. Oral antidiabetic drug
iii. Ayurvedic drugs

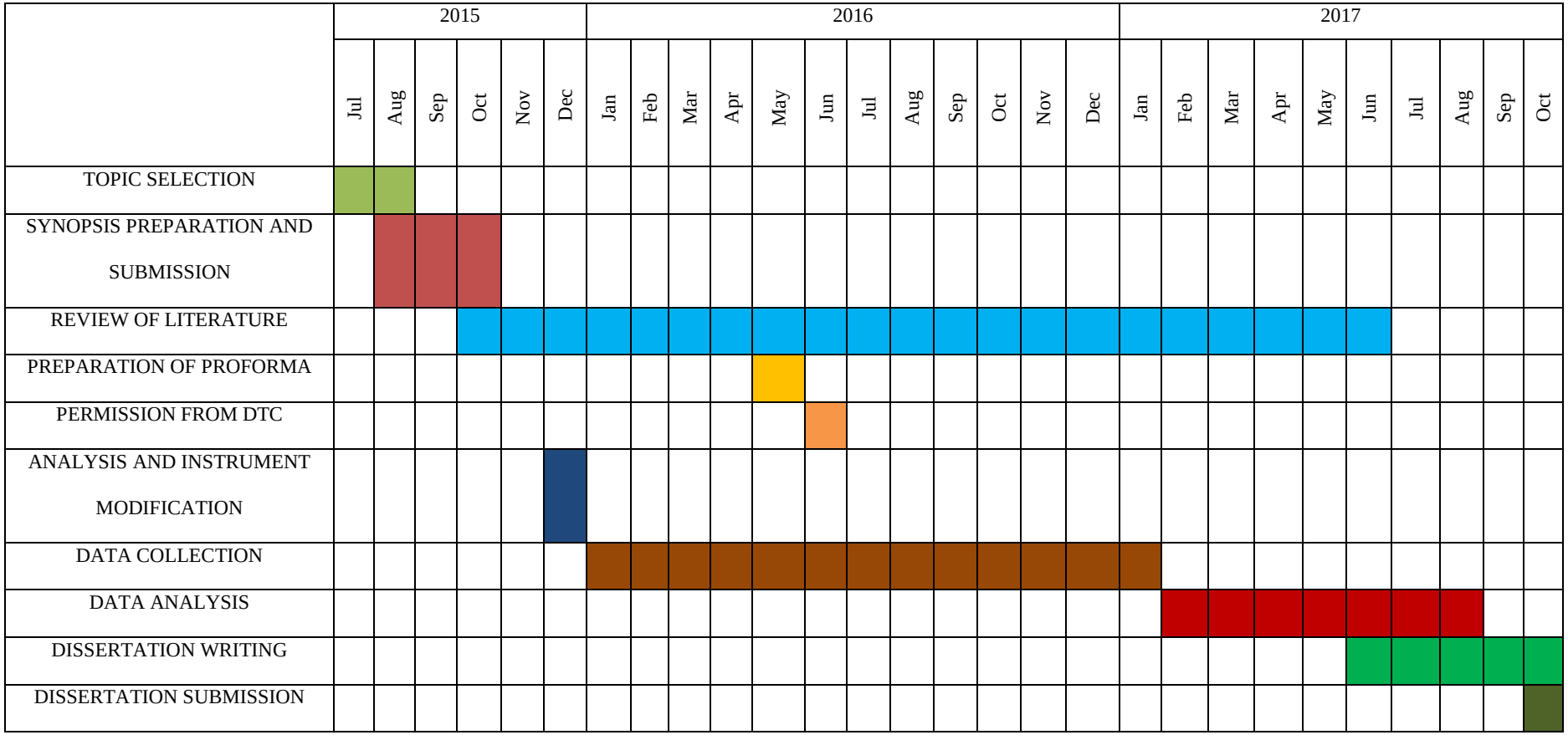
16). Family history of diabetes- Absent/One parent/Both parents

17). Anthropometric measurements-

i. Height (cm)
ii. Weight (kg)
iii. Waist circumference (cm)
iv. Hip circumference (cm)
v. Waist Hip ratio
vi. BMI

18). Random blood sugar (mg/dl) --------

GANTT CHART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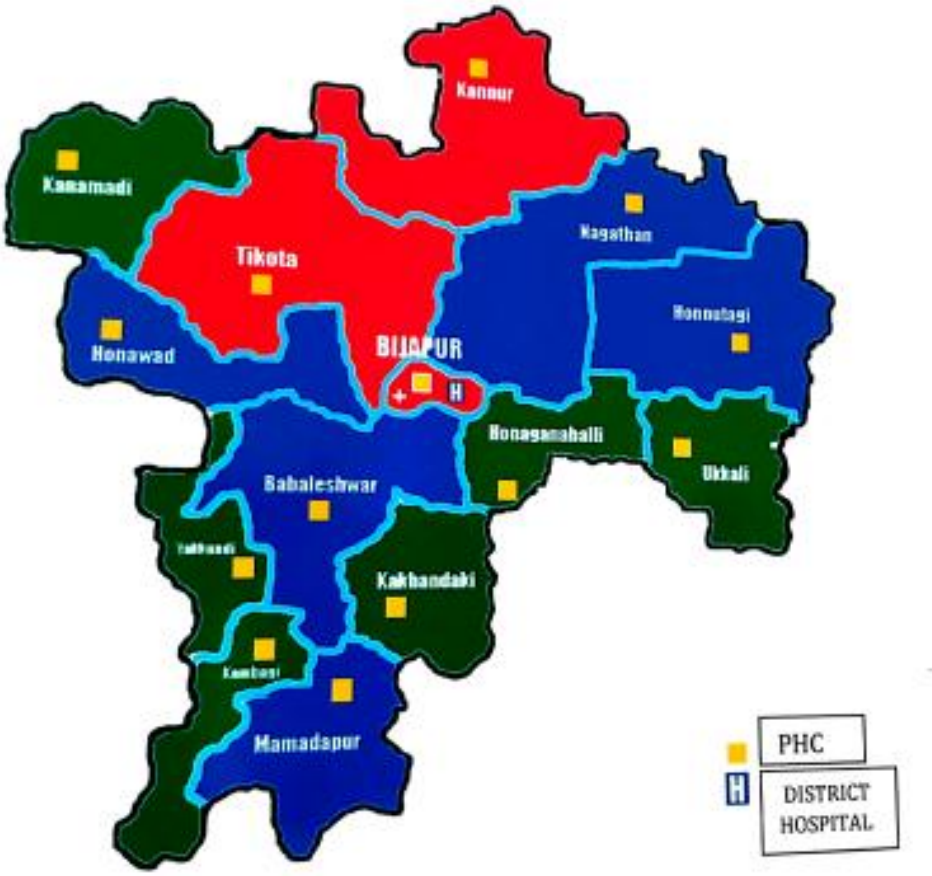
TOPIC SELECTION
SYNOPSIS PREPARATION AND SUBMISSION
REVIEW OF LITERATURE
PREPARATION OF PROFORMA
PERMISSION FROM DTC
ANALYSIS AND INSTRUMENT MODIFICATION
DATA COLLECTION
DATA ANALYSIS
DISSERTATION WRITING
DISSERTATION SUBMISSION

AREA MAP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Babaleshwar
Kakhandaki
Mamadapur
PHC
H
DISTRICT HOSPITAL

PHOTOGRAPHS