A STUDY TO ASSESS THE QUALITY OF LIFE (QOL) IN KNOWN TYPE 2 DIABETES MELLITUS PATIENTS AGED 30 -65 YEARS, RESIDING IN URBAN FIELD PRACTICE AREA OF SHRI B. M. PATIL MEDICAL COLLEGE, HOSPITAL & RESEARCH CENTRE, VIJAYAPURA.

By

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Dissertation submitted to

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In partial fulfillment of the requirements for the degree of

DOCTOR OF MEDICINE

In

COMMUNITY MEDICINE

Under the guidance of

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2018

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DECLARATION BY THE CANDIDATE

I, **Dr. TANUJA. P. PATTANKAR,** hereby declare that this dissertation entitled **"A STUDY TO ASSESS THE QUALITY OF LIFE (QOL) IN KNOWN TYPE 2 DIABETES MELLITUS PATIENTS AGED 30 - 65 YEARS, RESIDING IN URBAN FIELD PRACTICE AREA OF SHRI B M PATIL MEDICAL COLLEGE, HOSPITAL & RESEARCH CENTRE, VIJAYAPURA"** is a bonafide and genuine research work carried out by me under the guidance of **Dr. SHAILAJA. S. PATIL,** M.D., Professor & Head, Department of Community Medicine, B.L.D.E.U's Shri. B. M. Patil Medical College Hospital and Research Centre, Vijayapura.

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LIST OF ABBREVIATIONS

DM	:	Diabetes Mellitus
T2DM	:	Type 2 diabetes Mellitus
WHO	:	World Health Organization
QOL	:	Quality of life
WHOQOL-BREF	:	World Health Organization Quality of Life Brief Scale
BC	:	Before Christ
BCE	:	Before Common Era
ADA	:	American Diabetes Association
IDF	:	International Diabetes Federation
ICMR	:	Indian Council of Medical Research
ICMR-INDIAB Study	:	Indian Council of Medical Research – Indian Diabetes
NUDS	:	National Urban Diabetes Survey
CURES	:	Chennai Urban Rural Epidemiological Study
IFG	:	Impaired Fasting Glucose
IGT	:	Impaired Glucose Tolerence
BMI	:	Body Mass Index
SF-20	:	Short Form Survey – 20 Item Scale
EUQOL	:	European Quality of Life Scale
HRQOL	:	Health Related Quality of Life
p value	:	Probability value
WESDR	:	Wisconsin Epidemiologic Study of Diabetic Retinopathy
NCD	:	Non Communicable disease

ABSTRACT

Introduction:

Type 2 Diabetes Mellitus is becoming one of the major public health problems in both developing and developed countries. The incidence and prevalence of diabetes is increasing globally. Currently, India is the country with second highest number of people living with type 2 Diabetes Mellitus. The overall prevalence of diabetes in India ranges from 6.1 - 19.5%. The prevalence in Karnataka is 12.4%. Diabetes is estimated to be responsible for 109 thousand deaths, 1157 thousand years of life lost, and for 2263 thousand disability adjusted life years (DALYs).

Diabetes and its complications are leading cause for morbidity and mortality, which negatively affects the quality of life. Hence, quality of life evaluation has emerged as an important outcome measure for chronic disease management

Very few studies have been undertaken to understand the role of socio demographic factors and quality of life among known type 2 diabetic populations at community level. Our study was done to know the scenario of Quality Of Life among type -2 diabetic population residing in urban slums of the field practice area BLDEU's Shri B M Patil Medical College, Hospital and Research Center, Vijayapur.

Objectives:

1. To assess the Quality of life (QOL) and socio demographic factors associated with known type 2 diabetic people aged 30 - 65 yrs residing in urban field practice area of Department of Community Medicine, Shri B M Patil Medical College, Hospital and Research Centre.

2. To understand the association of BMI, Waist circumference, Blood pressure and Blood glucose levels (HbA1c) with QOL in the study participants.

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Materials & Methodology:

It was a cross-sectional study carried out in urban field practice area of Shri. B. M. Patil Medical College, Vijayapura. All known type 2 diabetics in the age group of 30 – 65 yrs, who fulfilled the selection criteria, were included in the study. Validated WHOQOL – BREF scale was used to assess the QOL, semi – structured questionnaire was used to assess the socio – demographic variables and PHQ-9 item scale was used to assess depression. Height, weight, abdominal circumference and blood pressure were measured. HbA1C levels were checked using single use HbA1C Now+ kit by BHR diagnostics for all the participants.

Statistical Analysis:

Data was compiled in Excel sheet and analyzed using SPSS ver. 16. Descriptive data was analyzed as frequencies, percentages and diagrams. Categorical variables were analyzed using chi – square test. Linear regression test was applied to assess the perceived QOL among study participants.

Results:

Majority of the known type 2 diabetics were in the age group of 30 – 40 yrs (36.7%). 56.3% of the study participants were overweight and obese (i.e., BMI >25kg/m^2, as per Asian Indian Classification). Hypertension was seen in ≈28% and pre – hypertension was in 55% of study participants. 12% of the participants had blood sugar levels >8% and among them 89.4% had UTI, 47.3% had neuropathy, 21% had foot ulcers and 26.3% had retinopathy. Mean score in physical health domain was around 50.5, environmental domain was 50.0, psychological domain was 47.0 and social domain was 45.8. Some of the indicators like age, gender, BMI, depression,

alcohol and tobacco consumption were found to be affecting quality of life among study participants. Perceived QOL was better in males than females, whereas females had better overall QOL domain scores.

Conclusion:

Reduced Quality of life is a major outcome of chronic disease management like Type 2 Diabetes Mellitus. The findings from this study show that half of the study population had poor QOL in all four domains, which implicates the need for holistic care for diabetic patients, with equal importance to treatment & life style modification will help them to lead a long and productive life.

CONTENTS

LIST OF TABLES

LIST OF FIGURES

INTRODUCTION

Diabetes is a major chronic disease both in terms of number of persons who suffer from it and its significant relation with morbidity and early mortality[1]. Previously, it was considered to have minor implication on world health, but now it is a major threat of public health importance globally[2].

Last two decades have seen an explosive increase in the number of people diagnosed with diabetes mellitus worldwide. There are two major types of diabetes, viz., type 1 diabetes (primarily an autoimmune disease) and the type 2 diabetes (insulin resistance and/or abnormal insulin secretion)[3]. Frequency of type 1 diabetes is low, relative to type 2 diabetes, which accounts for over 90% of global cases[2].

Prevalence of type 2 diabetes mellitus (T2DM) has reached an epidemic proportion in many countries. It is estimated that 422 million adults were living with diabetes in 2014, compared to 108 million in 1980. The global prevalence (age-standardized) of diabetes has nearly doubled since 1980, rising from 4.7% to 8.5% in the adult population. This is relative to an increase in risk factors such as overweight or obesity. Over the past decade, diabetes prevalence has risen faster in low- and middle-income countries than in high-income countries. Diabetes cause 1.5 million deaths yearly. Increased blood glucose level causes an additional 2.2 million deaths, by increasing the risk of cardiovascular and other diseases. Forty-three percent of these 3.7 million deaths occur before the age of 70 years[3].

Among the top 10 countries with the largest number of diabetic adults, five are in Asia. China tops the list with 90.0 million followed by India which has 61.3 million persons affected by diabetes. It is more alarming in developing Asian countries, as the

rise in prevalence of type 2 diabetes is among young adults. People in Asia are particularly at risk of diabetes, compared to western counterparts, due to their change in the life style pattern and white rice intake[2].

The numbers of type 2 diabetic patients in India are estimated to rise to 129.7 million by 2030. These figures probably are underestimation, as the prevalence data are mostly available from urban areas and reports from rural areas are scanty. India is largely a rural nation and the recent available reports indicate rising prevalence of the disease in the rural areas also[4].

Over the past few decades, various studies have been done in India to estimate the prevalence of diabetes. But, most of these studies have been small and focused mainly on specific towns, villages, or cities[5]. Hence these data cannot be drawn for whole of the population. But few multi-centric studies were also conducted such as, CURES (Chennai Urban Rural Estimation Studies) using WHO criteria which gave a crude prevalence of diabetes as 15.5 per cent while that of IGT (Impaired Glucose Tolerance) was 10.6 per cent[6]. The WHO-ICMR National NCD (Non Communicable Disease) risk factor surveillance study reported frequency of self-reported diabetes as 4.5%, in urban population it was 7.3% and rural population 3.1%[7]. These studies also reported three-fold higher (18.9/1000 person-years) mortality in diabetes compared to non-diabetics[8].

Type 2 diabetes and its complications are leading cause for morbidity and mortality in the world and they even have negative impact on the health and quality of life of the sufferers[9].

Unlike other diseases, this disease needs more stringent attention and careful monitoring. Diabetic patients have to undergo lifestyle adjustments such as timing of

food intake, type of food, regular exercise, daily medications, blood glucose monitoring and many more. These life style changes place unique demands on individual as well as on the family. Failure to follow any of these may lead to serious consequences. Hence, the primary goal of diabetic treatment is to maintain the glycemic index in normal range so as to minimize the development of complications related to diabetes mellitus[10].

Quality of life is increasingly recognized as an important health outcome, representing the ultimate goal of health for all interventions. With increase in prevalence of Diabetes in India, it becomes important to assess the quality of life[11].

Quality of life is defined by WHO as, "individuals' perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns"[11].

Very few studies have been undertaken to understand the role of socio demographic factors and quality of life among known type 2 diabetic populations at community level. Our study was done to know the scenario of Quality Of Life among type -2 diabetic population residing in urban slums of the field practice area BLDEU's Shri B M Patil Medical College, Hospital and Research Center, Vijayapura

OBJECTIVES OF THE STUDY

1. To assess the Quality of life and Socio demographic factors associated with known Type 2 Diabetes Mellitus patients aged 30 - 65 yrs residing in urban field practice area of Department of Community Medicine, Shri B M Patil Medical College, Hospital and Research centre.

2. To understand the association of BMI, Waist circumference, Blood pressure and Blood glucose levels (HbA1c) with Quality of life in the study participants.

REVIEW OF LITERATURE

History of Diabetes Mellitus:

Diabetes has been distressing health for thousands of years. A suspected case of diabetes was first documented by Egyptians dating 1550 BCE in manuscripts. Prehistoric Indians like Charaka in 600 BCE were also aware of this disorder, they had mentioned it as, "a mysterious disease causing thirst, enormous urine output, and wasting away of the body with flies and ants attracted to the urine of people" and they called it as Madhu-Meha. The name "Diabetes" was termed by Apollonius of Memphis in 250 BC, which means "to go through" or draw off as this disease drains fluid from the body than a person could drink. Later "Mellitus" was coined, which is a Latin word, meaning "Sweet Urine"[12]. Ancient documents illustrate that Indian, Chinese, Japanese, Persian, Greek and Korean doctors were aware of this disorder, but they could not ascertain its cause. Previously, it was thought that diagnosis of diabetes was likely to be a death punishment. The American Diabetes Association (ADA) in 1910 reported that, medical personnels took the prime step in the way of discovering its cause and treatment mode. Edward Albert Sharpey-Shafer was the first to discover that in diabetic patients, pancreas was unable to produce chemical which the body uses to break down glucose, which he later termed as "insulin". Therefore the Physicians started promoting the fasting diet collectively with regular work out to battle Diabetes. In spite of all the attempts to manage the disorder, people with diabetes died prematurely[13].

In 1921, two Canadian scientists Frederick Grant Banting and Charles Herbert Best successfully extracted insulin from healthy dogs. They injected this extracted insulin into diabetic dogs and looked for the improvement. Though insulin injection

was successful in combating against diabetes, few patients were unresponsive to this treatment. Types of diabetes based on insulin sensitivity, was distinguished by Harold Himsworth in 1936. He defined them as "insulin-sensitive" and "insulin-insensitive." Presently, these are commonly called as "type 1" and "type 2" diabetes mellitus. Type 2 diabetes was not treated effectively for many years. ADA reported that, oral medications for type 2 diabetes were finally developed in 1950s. These drugs helped to control the blood sugar levels, their action was by stimulating the pancreas to produce more insulin[14].

Portable glucose meters were invented in 1969 they were large in size, and since then, they have been reduced to hand-held calculator size. They are the key tool in management of diabetes today. They are used in monitoring the blood sugar levels at home, work, or anywhere else. They produce fairly accurate results[14]. Recently even HbA1c kits are being available which calculates the blood sugar level for past three months. This has improved the present day monitoring and treatment modalities of diabetes mellitus.

First Glucometer: **Present day Glucometer:**

HbA1C single use kit

Definition:

"Diabetes mellitus is described as a disorder of multiple etiology characterized by chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action or both"[15].

Diagnostic criteria of Diabetes Mellitus:

a. Classification and diagnostic criteria of Diabetes Mellitus has been reviewed time to time. Previously, WHO has published four technical Reports on diagnostic criteria of diabetes in the years 1965, 1980, 1985 and 1993 and the recently another report is published in 2003. Over the years there has been significant changes in the diagnostic criteria and classification of diabetes, they are summarized as:[16]

	1965	1980	1985	1999	2003
Normal Fasting Glucose	Not specified	Not Defined	Not Defined	<6.1mmol/l	Not Defined
2-h glucose	<6.1mmol/l			Not specified but <7.8mmol /l implied	
Diabetes Fasting Glucose	Not specified	≥8mmol/l or	≥7.8mmol/l or	≥7mmol/l or	≥7mmol/l or
2-h glucose	≥7.2mmol/l	≥11mmol/l	≥11.1mmol/l	≥11.1mmol/l	≥11.1mmol/l

IGT **Fasting Glucose** **2-h glucose**	Borderline state 6.1-7.1mmol/l	<8mmol/l & ≥8 – 11.1 mmol/l	<7.8mmol/l & ≥7.8 – 11.1 mmol/l	<7mmol/l & ≥7.8 – 11.1 mmol/l	Not required ≥7.8 – 11.1 mmol/l
IFG **Fasting Glucose** **2-h glucose**	Not defined	Not defined	Not defined	≥6.1 – 7 mmol/l & 〈7.8mmol/l	5.6 – 6.9 mmol/l Measurement not recommended

Etiological classification of Diabetes Mellitus:[15,16]

1. **Type -1 Diabetes Mellitus:** main cause is Beta – cell destruction, leading to absolute insulin deficiency, may be either,

   - Idiopathic or
   - Autoimmune

2. **Type -2 Diabetes Mellitus:** It is the commonest form of diabetes and characterized by defect in insulin action and/or insulin secretion, either of which may be the predominant feature.

3. **Other specific types**

   - Genetic defects of beta – cell function
   - Genetic defects in insulin action
   - Disease of the exocrine pancreas
   - Endocrinopathies
   - Drugs – or chemical induced
   - Infections
   - Uncommon forms of immune – mediated diabetes
   - Other genetic syndromes sometimes associated with diabetes.

Type 2 Diabetes mellitus (type 2 DM):

Diabetes mellitus (DM) is one among the oldest disease known by man[17]. In 1988, Type 2 DM was described as a element of metabolic syndrome[18]. Type 2 DM (formerly known as non-insulin dependent DM) is the most common type of DM characterized by body's ineffective use of insulin.

Type 2 DM is an outcome of interaction between environmental, genetic, and behavioral risk factors[1,20]. People living with type 2 DM are exposed to various forms of short- term and long-term complications, which frequently lead to early onset death. This increased tendency of morbidity and mortality is because of uniqueness of type of DM which is ice berg phenomenon, characterized by insidious onset and late recognition, especially in resource-poor developing countries like India[21].

Epidemiology in World:

Some of the non-communicable diseases like DM have dramatically increased since last decade. The World Health Organization (WHO) had estimated that 9% of the world's population was diabetics in 2014, and around 90% of them were having type 2 diabetes mellitus. It is estimated that, type 2 diabetes leads to 5 million deaths every year, usually from cardiovascular diseases (CVD). It is expected to rise to 7th cause of death globally by 2030[22]. Type 2 DM is the disease associated with life style changes; therefore its load is raising in low and middle income countries, as a result of influence of recent urbanization and industrialization.

In previous decade, various organizations have given reliable estimate of both true and predicted prevalence of diabetes mellitus worldwide. The large inhabitants of the Western Pacific (WP) region add to the absolute numbers, whilst the percentage

prevalence is highest in the Middle East and North Africa. In reality, Saudi Arabia has surprisingly high population prevalence of 20%[23] whereas in South East Asia, the prevalence of type 2 DM is 8.7%, as estimated by WHO. It has also estimated that by year 2035, this trend would increase to 9.1% of prevalence in the region[22].

The growing prevalence of type 2 diabetes has a enormous impact on international health because of its morbidity and mortality[23]. The data of International Diabetes Federation [IDF] propose that every year 5 million deaths are solely attributed to diabetes. This is indeed more than the burden of HIV/AIDS, tuberculosis and malaria pooled. Diabetes is most important cause of CVD, acquired blindness, kidney failure and of lower leg amputations. As a consequence, global health expenses on diabetes is likely to be as high as 673 billion dollars and it will go up as the pandemic progresses[22].

Epidemiology in India:

India is the epicenter for diabetes mellitus epidemic in the world[24]. It has second highest number of population with the diabetes mellitus i.e., ~69 million individuals as of 2015[24]. India has topped the world with the highest number of people living with type 2 diabetes mellitus in 2000, followed by China and United States in second and third place respectively[25]. Hence it is called Capital of diabetes mellitus.

The studies to assess the prevalence of diabetes mellitus in India started only in the middle of the twentieth century[24]. The first multicentre study on type 2 diabetes mellitus was started in 1971 by the Indian Council of Medical Research (ICMR). It was a prevalence study, which done in six urban areas and surrounding rural areas (Ahmedabad, Kolkata, Cuttack, Delhi, Pune and Trivandrum were the cities).

Prevalence was found to be 2.1% in the urban areas and 1.5% in the rural areas[26]. Subsequently, numerous other epidemiological studies were done on diabetes mellitus in different part of the country[25]. These studies used varying methodologies, sampling techniques and diagnostic criteria. But, they reported clear increasing tendency in the prevalence of diabetes mellitus. This trend has been most clearly visible in the southern Indian city of Chennai, where the results of a sequence of studies done from 1989 to 2004, revealed 72% raise in the prevalence of diabetes mellitus[27].

More than two decades later of ICMR project in 2001, the National Urban Diabetes Study (NUDS) sampled people from six major metropolitan cities of India and showed the prevalence ranging from least of 9.3% in Mumbai to highest of 16.6% in Hyderabad[28].

Previously until 2011, the estimated prevalence of diabetes mellitus by International Diabetes Federation (IDF) in India was based on smaller studies. However, none of these studies were fully representative of India. Presently the ongoing ICMR–India Diabetes (ICMR– INDIAB) study aims uniform sampling techniques and diagnostic criteria in a representative sample sample from rural and urban areas[29]. Results from phase I of the study (covering four regions: Tamil Nadu, Maharashtra, Jharkhand and Chandigarh, estimated 62 million individuals had diabetes mellitus and 77 million had pre-diabetes in 2011[5] .

Common Risk Factors for type 2 DM:[22]

Age

Recently most of the focus has been shifted to obesity as most important modifiable risk factor for type 2 DM. But, age is in fact is one of the major non modifiable risk factor for the occurrence of type 2 diabetes mellitus. Other disorders of glucose

metabolism such as Impaired Fasting Glucose (IFG) and Impaired Glucose Tolerance (IGT) are also progressively increasing in older age group. It is estimated that after the age of 80 years the possibility of having a fully normal glucose metabolism is about 30%. This suggests that disorder of glucose metabolism, is a part of a normal aging process.

Obesity

Obesity is a potential modifiable risk factor for type 2 diabetes. Hence, there is an exponential association between Body Mass Index and risk of type 2 diabetes. Central obesity seems to be most conferring cause of the risk of type 2 DM. This also explains the amplified risk in men, who have a increased central obesity, compared to women of similar BMI. It should be noted that obesity itself is a reflection of various metabolically unfavorable lifestyle factors such as excessive calorie intake, reduced physical activity.

Gender

At present, the prevalence of diabetes is similar among men and women. But it must be noted that, there are some indications that at the same level of obesity, man have increased risk of type 2 DM than women, as they have more visceral adipose tissue distribution.

Ethnicity

It is difficult to cut apart cultural lifestyle factors from genetic factors, there seems to be an surplus genetic risk of diabetes in certain ethnic groups such as South Asians and the native people of Australia. However, it is not only the genetic per se, but also the influence of affluence on the genetic predisposition. This explains the relative increase in diabetes prevalence in recent years.

Socioeconomic factors

It is estimated that two third of the diabetic patients live in urban area. But population of lower socio economic classes are also being affected recently and the reasons are still not understood well, but unhealthier lifestyles may be an important factor. Internationally, lower-middle income countries contribute to most of the prevalence. This is possibly because; these countries are recently urbanized, which has drastically changed their lifestyle and longevity.

Physical activity

Increased physical activity has an advantageous effect on glucose metabolism and also reduces the risk of obesity. However, sedentary life style is more important risk factor than the lack of high intensity physical activity. Particularly in children, there are clear associations between sedentary behaviors (such as TV viewing) and the risks of becoming obese.

Diet

Over the years, some of the dietary factors have been considered as risk factors for diabetes. As there is strong relationship between diabetes and obesity, evidence for prevention of diabetes derived from studies on dietary intervention coupled with increased physical activity among diabetic patients has shown apart from total caloric intake, certain dietary factors have also been implicated as risk for diabetes. Particularly intake of sugar sweetened beverages; high carbohydrate diet and fatty diet etc. are most commonly identified risk factors. Coffee and high fiber diet are implicated with low risk of diabetes mellitus.

Stress

Change in work patterns and lack of sleep have also been implicated as risk factors for type 2 diabetes. This may be the result of disruption of the biological clock or due to work related stress, which is not clear, but the relationship has repeatedly been shown to exist.

Cortisol and (nor) adrenalin are the hormones fluctuating in the time of stress. They are known for their effect on glucose metabolism and short term increases in glucose in response to stress. But still there are no consistent epidemiological studies for establishment of relation between (long-term) stress and risk of type 2 diabetes.

Quality of Life in type 2 DM:

Diabetes mellitus is a common NCD that affects quality of life (QOL) of patient adversely. Hence, in this scenario measurement of QOL as an outcome for management of type 2 DM is of utmost importance[30]. Quality of life has been defined by WHO as "individuals' perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns"[31].

Quality of life is important, as they foresee the individual's capacity to manage the disease and maintain long-term health and well-being. It is rightly said by Singh H *et al.* in his article in 2006, "Quality of life is also increasingly recognized as an important health outcome in its own right, representing the ultimate goal of health for all interventions"[25]. As there is sharp rise in prevalence of Diabetes among Indians it is important to evaluate the QOL for better care and control.

In this regard some of the studies have been done to assess the QOL among known type to DM patients using different scales for measurement of QOL like WHOQOL – BREF scale, SF – 20, EUQOL Scale, Indian Diabetic Score Scale etc. Any type of scale used, showed similar results that QOL depends on factors like BMI, Waist Circumference, glycemic control, mental status etc.

A study by Harish Kumar Somappa *et al.* in Kolar in 2014 showed that mean age of male participants were 59.56 ± 9.64 and females were 60.90 ± 7.51. They used WHOQOL – BREF for assessing QOL. In their study, mean score of QOL with respect to physical, psychological, social and environmental domains were higher in females than males (p<0.01). QOL domains and other continuous variables showed that there is significant positive correlation between age and physical, psychological, social and environmental domains (r = 0.864, 0.396, 0.549, 0.420 respectively and p<0.001). Logistic regression revealed that increase in age and HbA1c acts as independent factors to assess the QOL[11].

The study Genga EK *et al.* in 2009 on 139 patients attending the Diabetic clinic at Kenyatta National Hospital, using WHOQOL – BREF scale showed that the study population was predominantly female (61%) , majority were in 40 - 60yrs, mean history of diabetes was 5yrs, and 75% of the participants had more than one complications. Majority (75%) of the study participants maintained their HbA1C levels poorly, with mean score of 8.04%. Majority of the study participants (84%) achieved a good score on the HRQOL scale using the WHOQOL-Bref tool. The determinants of HRQOL in this study were: age of study participants, duration of diabetes, presence of complications and income related factors. Age of the study subjects had significant association only in the social domain of HRQOL with a p-value of 0.037. Level of income had a significant association with overall HRQOL

score (p-value of 0.029), psychological domain (p value of 0.023) and in the social domain (p-value of 0.029). Health care financing was significantly associated with psychological domain (p-value 0.006) and environmental domain (p-value 0f 0.04) and overall score (p-value 0.011). There was an association between employment status and HRQOL. Having a job improved the scores in physical domain (p value of 0.013) and social domain (p value of 0.020). Duration with diabetes had significant association with physical domain where the p value was 0.007. The HRQOL of the study subjects was associated significantly with the number of complications. Indeed the association of complications with the HRQOL involved physical domain (p-value of <0.0001) and psychological domain (p-value of 0.041) which directly impacted on the overall total score (p value of 0.041)[31].

A cross-sectional study was done in Bulgaria in 2016 among 90 patients with type 2 diabetes mellitus (T2DM). Health-related quality of life was measured using the 36-item Short-Form Health Survey (SF-36). The study reports revealed that the participants' age ranged from 32 to 88 years old and mean age was 63.0 years (SD 0.96). Females were 52.9%, married people were 74.3% and participants residing in urban area were 61.4%. it was observed that diabetes impacts negatively on all life aspects. The duration of diabetes and complications related to same had influential effect on QOL and negatively affect it and this was statistically significant. It inferred from this study that, better quality of life of patients with diabetes can be achieved by preventing complications and effective management[32].

Another cross-sectional study was done at Neyshabur, Iran using Iranian version of WHOQOL - BREF, from April to July 2012. A total of 1847 paricipants with type 2 diabetes were included in the study. The mean age of the study participants was 59.65 ± 12.3 yr. The majority of participants were female (69.8%).

The overall observed Cronbach's alpha coefficient for WHOQOL-BREF was 0.93 and for each domain it ranged from 0.69 to 0.86. The total mean score of WHOQOL--BREF was 12.18. The lowest and the highest mean scores were observed in Psychological health domain (11.73) and Social relationship domain (12.66), respectively. multiple linear regressions showed that education level, marital status and household income were significantly associated with all domains of WHOQOL--BREF (P < 0.05)[33].

Another study at CMC, Vellore showed the mean total score of the WHOQOL scale as 58.05 (95% CI, 22.18–93.88). Domain-wise, 63% had good physical, 69% had good psychological, 27% had good social and 85% had good environmental QOL scores. Males, currently married and those with BMI more than 25 had a statistically significantly better QOL compared to their counterparts. They concluded that diabetes impairs the QOL of patients but not to a larger extent. There is a need to target type 2 DM and improve the QOL of both male and female. Widow, separated and non-obese diabetics also had risk of a poor QOL. They also inferred that QOL should be routinely assessed in diabetic clinics[34].

QOL and Complications of type 2 DM:

The studies in this regard have been constantly showing that complications, generally two or more complications, are associated with poor QOL. In some studies, it is frequently seen that complications are removed as exclusion criteria, which explains its possible confounding effect[34]. Studies done by Richard R *et al.,* Payrot M *et al*. found that the presence of two or more complications among type 2 diabetics was linked with a significant raise in the possibility that patients had clinically significant depression[35,36]. Other studies like the one done by Eiser C *et al.* showed that the presence of complication was associated with decreased QOL [37].

Jacobson and his colleagues reported that decreased QOL on SF-36 scale, when associated with greater severity of complications in patients with either type of diabetes[38]. It was observed that, among those who had Type 2 diabetes with less than 2 complications, the number of complications was weak predictor of QOL in SF36 scale scores, similar pattern of findings was reported for the association between number and severity of complications and scores on QOL scales, with treatment satisfaction and disease impact scales consistently sensitive to severity of complications and less consistently responding to number of complications[35]. But, Trief *et al.* reported that number of complications was a strong predictor of QOL diabetes and treatment satisfaction scores in a type 1 diabetic patients[39]. Others have found that the presence of neuropathy, cardiovascular disease or end-stage renal disease was associated with decreased scores of QOL; The presence of end-stage renal disease was associated with markedly increased functional impairment as measured by the Sickness Impact Profile; and the presence of nephropathy was associated with greater health worries and reduced perceived health in patients with diabetes. Several researchers have found increased depression and negative life experiences during the two years after diagnosis with proliferative diabetic retinopathy.

These psychosocial disruptions existed regardless of the severity of the visual impairment and were maintained even after lost vision was regained. It has been estimated that 50% of diabetic men with impotence have a significant emotional overlay attributable to depression or anxiety that contributes to erectile dysfunction[35].

QOL and Glycemic control (HbA1c):

Over past few years there has been an increasing research on finding out the relationship between glycemic control and QOL in people with type 2 diabetes, and a number of these studies suggest that there is a significant relationship between two. A study by Rubin RR *et al*. using SF-36 to assess quality of life found significant associations between HbA1c and some SF-36 scales in some sub-populations (30). In the Wisconsin Epidemiologic Study of Diabetic Retinopathy (WESDR), Klein *et al*. found that SF-36 general health and overall self-rated health scores were associated with HbA1c levels among younger subjects only (i.e. diagnosed before 30 years and taking insulin)[40]. Wikblad *et al*. reported that scores on the Quality of Life Scale were lowest for those with the highest HbA1c levels (8.1%), highest for those with HbA1c levels 7.1–8.0%, and intermediate for those with the lowest HbA1c levels 7.0%[41]. On the basis of these data, Rubin RR *et al.* reported that "it can be advocated that there may be a curvilinear relationship between HbA1c level and health-related quality of life", perhaps as a result of decrements in quality of life associated with more complex treatment regimens or increased incidence of hypoglycemia[35]. A few studies have found that there is no significant relationship between HbA1c levels and diabetes-specific QOL, but the HbA1c levels of the participants in these studies were quite low, averaging about 7.0%, so the restricted range of glycemia may have contributed to the null finding[35].

QOL and gender:

A number of researchers have found that QOL is better among men than women suffering from type 2 diabetes mellitus. This is reliable with reports on gender differences in health-related quality of life (HRQOL) in the general population. On the contrary, a study by Harish Kumar Somappa *et al*. using WHOQOL BREF scale

showed that males had lower score (i.e., better QOL) with all the four domains compared to females[11]. Eljedi A *et al* observed that females has lower QOL than males[42]. Similarly Rubin RR observed that men generally report better quality of life than women and younger people report better quality of life than older people[35]. Rubin RR *et al*. also found that treatment satisfaction was better and diabetes burden poor in men than in women and those men were significantly less likely to report symptoms of depression or anxiety, this was consistent with the presence of clinical disorder among women than men[35]. Hence these findings, propose that diabetic men have an advantage over diabetic women in health-related quality of life.

QOL and Psychosocial Factors:

Some have suggested that HRQOL in people with type 2 diabetes may be affected by psychosocial factors such as health beliefs, social support, coping strategies and personality traits[35]. For example, Rose *et al*. found that subjects who reported feeling more socially capable and who received more support for diabetes treatment from family and friends, and who coped more actively, reported higher levels of performance and wellbeing as well as higher levels of QOL[43]. Rubin RR *et al*. reported that, "it can be understood that coping strategies and personality traits significantly co varies with all quality of life realms, and has a greater effect than the presence of complications on overall health-related quality of life. Other researchers have reported higher levels of perceived social support were associated with higher levels of social functioning in diabetic patients on intensive insulin treatment"[35].

Diagnosis and Treatment of Type 2DM:

Screening and Diagnosis:

Tests for screening and diagnosis of DM are readily available. The test suggested for screening is similar to that for making diagnosis of type 2 DM. The positive result of screening is equivalent to diagnosis of either pre-diabetes or type 2 diabetes mellitus[19]. It is estimated that about 25% of patients with type 2 DM, already have microvascular complications at the time of diagnosis, which suggests that they have had the disease for more than 5 years at the time of diagnosis[44]. Screening and diagnosis of type 2 DM is still based on the American Diabetic Association (ADA) guidelines of 1997 or World Health Organization (WHO) National diabetic group criteria of 2006, which is for a single raised glucose reading with symptoms (polyuria, polydipsia, polyphagia and weight loss), otherwise raised values on two occasions, of either fasting plasma glucose (FPG) ≥7.0 mmol/L (126 mg/dL) or with an oral glucose tolerance test (OGTT), two hours after the oral dose a plasma glucose ≥11.1mmol/L (200 mg/dL)[16]. The 1997 ADA recommendations for diagnosis of DM focus on the FPG, while WHO focuses on the OGTT. The glycated hemoglobin (HbA1c) is now useful for determining blood sugar control over time[16]. However, practicing physicians regularly use other measures in addition to those recommended. In July 2009, the International Expert Committee (IEC) recommended the additional diagnostic criteria of an HbA1c result ≥6.5% for DM. This committee suggested that the use of the term pre-diabetes may be phased out but identified the range of HbA1c levels ≥6.0% and <6.5% to identify those at high risk of developing DM[45].

As there is no definite threshold of HbA1c at which normality ends and DM begins as in glucose based tests. The IEC has elected to recommend a cut-off point for DM diagnosis that emphasizes specificity, commenting that this balanced the stigma

and cost of mistakenly identifying individuals as diabetic against the minimal clinical consequences of delaying the diagnosis in a patient with an HbA1c level <6.5%[19]

Management of type 2 DM:

Studies have shown that there is significant reduction in the incidence of type 2 DM through lifestyle and diet modification. A combination of maintenance of body mass index of 25 kg/m^2, eating high fiber and consuming more of unsaturated fat compared to saturated and trans-fats and, regular exercise, abstinence from smoking and moderate consumption of alcohol maintains glycemic index under normal range[19]. Suggesting that majority of type 2 DM can be prevented by lifestyle modification. Patients with type 2 DM should receive a medical nutrition evaluation; lifestyle recommendations should be tailored according to physical and functional ability[37].

Pharmacological Agents

Biguanides

Biguanides, of which metformin is the most commonly used in overweight and obese patients, suppresses hepatic glucose production, increases insulin sensitivity, enhances glucose, and decreases the absorption of glucose from the gastrointestinal tract[46]. A research article published in 2008 shows further mechanism of action of metformin as activation of AMP-activated protein kinase, an enzyme that plays a role in the expression of hepatic gluconeogenic genes.(10)Due to the concern of development of lactic acidosis, metformin should be used with caution in elderly diabetic individuals with renal impairment. It has a low incidence of hypoglycemia compared to sulfonylureas[47].

Sulfonylureas*:*

These are generally well tolerated but as they stimulate endogenous insulin secretion, they also carry a risk of hypoglycemia[46]. Elderly patients, with DM who are treated with sulfonylureas have a 36% increased risk of hypoglycemia compared to younger patients. Use of long acting sulfonylurea such as glyburide should be avoided in elderly patients with DM and use of short acting glipizide should be preferred[46].

Meglitinides

Repaglinide and nateglinide are non-sulfonylurea secretagogues which act on the ATP dependent K-channel in the pancreatic beta cells thereby stimulating the release of insulin from the beta cells, similar to sulfonylurea, though the binding site is different[48]. Meglitinides have a rapid onset and a short duration of action (4-6 hrs) and thus lower risk of hypoglycemia. They are given before meals for postprandial blood glucose control. Pre-prandial administration allows flexibility in case a meal is missed without increased risk of hypoglycemia[19].

Thiazolidinediones (TZD)

Thiazolidinedione is an insulin sensitizer, selective ligands transcription factor for peroxisomes proliferator-activated gamma. They are the first drugs to address the basic problem of insulin resistance in type 2 DM patients, whose class now includes mainly pioglitazone after the restricted use of rosiglitazone recommended by Food and Drug Administration (FDA) recently due to increased cardiovascular events reported with rosiglitazone[19]. Pioglitazone use is not associated with hypoglycemia and can be used in cases of renal impairment and thus well tolerated in older adults.

Alpha-Glucosidase Inhibitors

Acarbose, Voglibose and Miglitol have not widely been used to treat type 2 DM individuals but are likely to be safe and effective. These agents are most effective for postprandial hyperglycemia and should be avoided in patients with signifcant renal impairment. Their use is usually limited due to high rates of side-effects such as diarrhoea and flatulence. **Voglibose,** which is the newest of the drugs, has been shown in a study to signifcantly improve glucose tolerance, in terms of delayed disease progression and in the number of patients who achieved normoglycemia[19].

Incretin-Based Therapies

Glucagon-like peptide 1 (GLP-1) analogues are the foundation of incretin-based therapies which are to target this previously unrecognized feature of DM patho-physiology resulting in sustained improvements in glycemic control and improved body weight control. They are available for use as monotherapy, as an adjunct to diet and exercise or in combination with oral hypoglycemic agents in adults with type 2 DM[19].

Dipeptidyl-Peptidase IV Inhibitors

Dipeptidyl-peptidase (DPP) IV inhibitors inhibit dipeptidyl peptidase-4 (DPP-4), a ubiquitous enzyme that rapidly inactivates both GLP-1 and GIP, increase active levels of these hormones and, in doing so, improves islet function and glycemic control in type 2 DM. DPP-4 inhibitors are a new class of anti-diabetogenic drugs that provide comparable efficacy to current treatments. They are effective as monotherapy in patients inadequately controlled with diet and exercise and as add-on therapy in combination with metformin, thiazolidinediones, and insulin[19].

Insulin

Insulin is used alone or in combination with oral hypoglycemic agents (OHA). Augmentation therapy with basal insulin is useful if some beta cell function remains. Replacement of basal-bolus insulin is necessary if beta cell exhaustion occurs. Rescue therapy using replacement is necessary in cases of glucose toxicity which should mimic the normal release of insulin by the beta cells of the pancreas[50]. Insulin comes in injectable forms - rapid acting, short acting, intermediate acting and long acting.

Insulin analogues

Insulin therapy was limited in its ability to mimic normal physiologic insulin secretion. Traditional intermediate and long acting insulins (NPH insulin, lente insulin, and ultralente insulin) are limited by inconsistent absorption and peaks of action that may result in hypoglycemia. The pharmacokinetic profiles of the new insulin analogues are distinct from those of the regular insulins, and their onset and durations of action range from rapid to prolong. Currently, two rapid-acting insulin analogues, insulin lispro and insulin aspart, and one long-acting insulin analogue, insulin glargine, are also available[19].

Future in Drug Therapy Inhaled Insulin

The inhaled form of rapidly acting insulin which became available in 2006, after it was approved by both the European Medicines Evaluation Agency and FDA for treatment of type 1 and type 2 DM in adults[51]. It is a rapid acting form of insulin that was indicated for use in adults with type 1 and type 2 DM and has the advantage of delivery directly into the lungs[19].

Bromocriptine

Quick-release bromocriptine has recently been developed for the treatment of type 2 DM. However, the mechanism of action is not clear. Studies have shown that they reduce the mean HbA1c levels by 0.0% to 0.2% after 24 weeks of therapy[19].

Others

Inhibitors of the sodium-glucose cotransporter 2, which increase renal glucose elimination, and inhibitors of 11ß-hydroxysteroid dehydrogenase 1, which reduce the glucocorticoid effects in liver and fat. Insulin-releasing glucokinase activators and pancreatic G-protein-coupled fatty acid receptor agonists, glucagon-receptor antagonists, and metabolic inhibitors of hepatic glucose output are being assessed for the purpose of development of new drug therapy for type 2 diabetic patients[19].

Treatment Algorithm for type 2 DM for achieving blood glucose target:[52]

- Diagnosis of type 2 DM - Diet & exercise +/- OHA - Trail for 3months

→

- Add one OHA - Metformin preferred in overweight individuals - Trail for 3 months

↓

Add second medicine, usually an OHA, e.g. sulphonylurea trail for 3 months

↓ (left branch) ↓ (right branch)

- HbA1c >6.5-7% - Add a third OHA, e.g. a TZD or initiate insulin: preferred, if HbA1c >8% - Do not use OHA above maximal dose - Trail for 3 months

- HbA1c >7.3% - Add insulin, e.g. basal long acting analogue at bed time and filterate the dose weekly or Isophane at bed time and adjust the dose every 3-4 days to achieve target.

↓

- If the target is not achieved with 50 units of basal insulin, add a second dose of insulin, e.g. premixed insulin 30/70 - Give 2/3 of total dose before breakfast and 1/3 before evening meal Or - Institute basal bilus depending on the patient: rapid short acting before each meal and long acting analog of isophane - Cease OHA

Use of Complimentary Alternate System of Medicine in treatment of type 2 DM:

Complementary and alternative medicine (CAM) is defined as a group of diverse medical and healthcare systems, practices, and products that are not generally considered part of conventional Western medicine[53]. Regardless of the type of diabetes, patients are required to control their blood glucose levels with medication and/or by adhering to an exercise program and a dietary plan. Patient with type 2 diabetes mellitus are usually placed on a restricted diet and are instructed to exercise, the purpose of which primarily is weight control. If diet and exercise fail to control blood glucose at a desired level, pharmacological treatment is prescribed[54]. These treatments have their own drawbacks ranging from development of resistance to adverse effects[55].

Complementary and alternative therapy is not widely taught in medical schools nor widely practiced in hospitals. The use of CAM in the worldwide is increasing. In 1997, 42% Americans had used an alternative medical therapy. Total visit to complementary practitioners (629 million) exceed total visit to US primary care physicians (386 million)[56]. In Canada, a recent survey found that 75% people with diabetes used non-prescribed supplements (herbal, vitamin, mineral, or others) and alternative medications[57]. Overall research indicates that most people who use CAM therapies do so in addition to, rather than in place of conventional medical treatment[57] although some do not receive any concurrent conventional medical care. CAM for diabetes has become increasingly popular the last several years. Alternative therapies with antidiabetic activity have been researched relatively, extensively, particularly in India[55].

Alternative therapy used for lowering the blood glucose in India is summarized in below table:[55]

Complementary and alternative therapy with mechanism for lowering blood glucose

CAT	Mechanism
Yoga	Improve in insulin sensitivity and decline in insulin resistance[30]
Massage	At an injection site increase serum insulin, thereby decrease blood glucose[151]
Acupuncture	Act on pancreas to enhance insulin synthesis, accelerate the utilization glucose, resulting in blood sugar[51]
Aromatherapy	Ameliorate the stress of coping with a lifelong chronic condition such as diabetes[137]
Momordica charantia	Not known (In diabetic rabbit models it possesses a direct action similar to insulin)[152]
Trigonella foenum graceum	Hypoglycemic effect may be mediated through stimulating insulin synthesis and/or secretion from the beta pancreatic cells of Langerhans.[153]
Gymnema sylvestre	This is attributed to the ability of gymnemic acids to delay the glucose absorption in the blood[154]
Azadirachta indica	Not known
L-Carnitine	Effect insulin sensitivity and enhance glucose uptake and storage[155]
Vanadium	Insulin mimetic with up gradation of insulin receptors[156]
Chromium	Facilitates insulin binding and subsequent uptake of glucose into cell[86]
Vitamin E	Potent lipophilic antioxidant activity with possible influences on protein glycation lipid oxidation and insulin sensitivity and secretion[156,86]

MATERIALS & METHODS

Topography of the study area:

AREA MAP OF UHTC BIJAPUR
(With Important Land Marks)

INDEX
- ■ SCHOOLS
- ■ MOSQUE
- ♣ TEMPLE
- ◉ WELL
- ■ HOUSES
- ■ SHOPS
- ⊕ UHTC
- ● IMMUNIZATION POINT

DEVGIRI GRAVE YARD
MUSLIM GRAVE YARD
MULLAGASI ROAD
OPEN AREA
COLLEGE ROAD
DARGA ROAD
POLICE GROUND
POLICE QUARTERS
WATER TANK ROAD
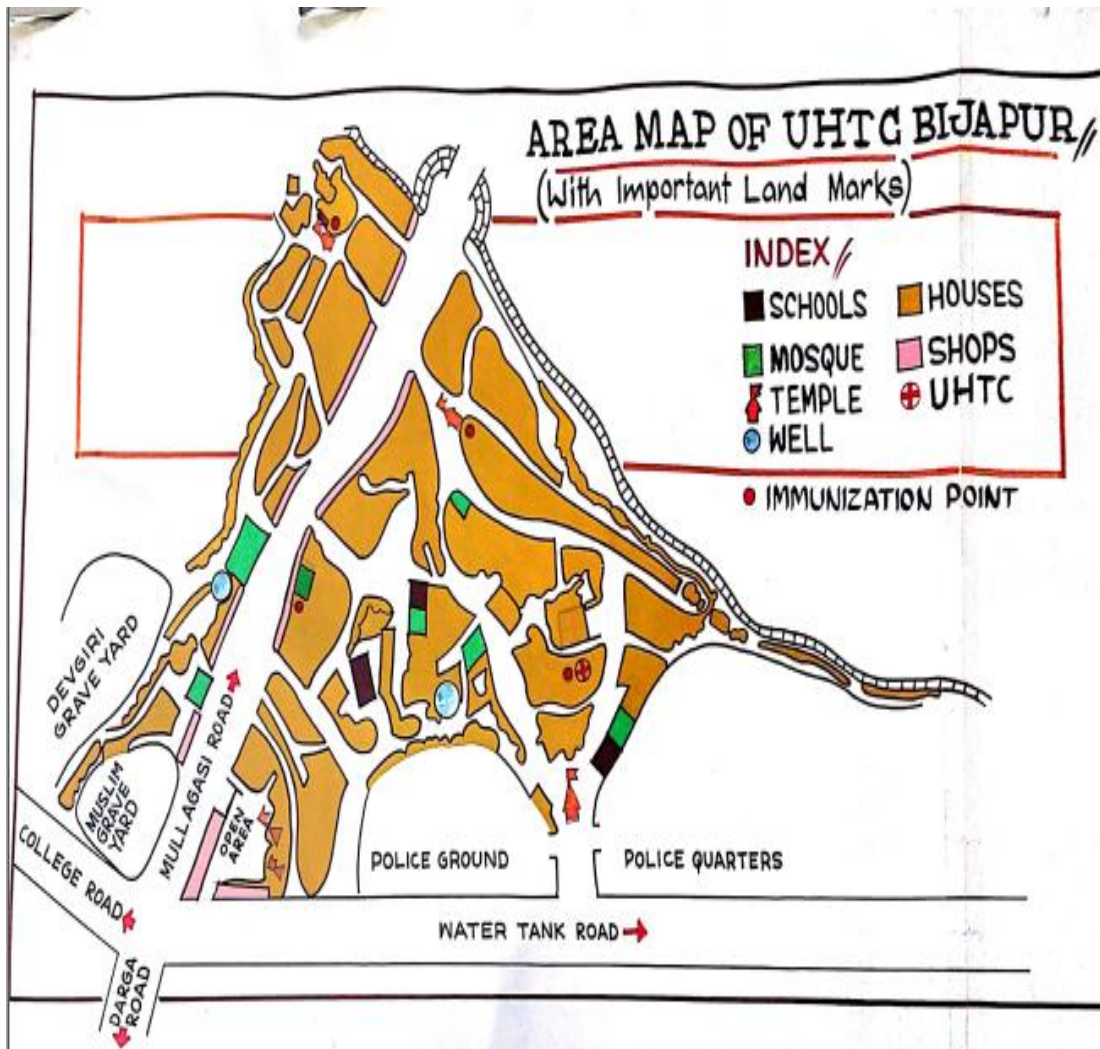
Study area:

Urban field practice area of Community Medicine Department of Shri B M Patil Medical College, Hospital and Research Centre, Vijayapura. This area comprises of six urban slums registered in slum board of Vijayapura, with around 10,000 people residing in the 1260 households.

Study population: People with known history of Type 2 Diabetes mellitus.

Study design: Community based Cross sectional study.

Study technique: Interview technique accompanied by anthropometric measurements, blood pressure measurement and blood glucose level measurement (using HbA1c kits).

Study period: 1st January 2016 – 30th December 2016

Sample size:

Sample size was obtained by taking prevalence of self reported type 2 diabetes mellitus as 10.22%[11] , in Karnataka at 95% confidence interval and 5% absolute allowable error.

The formula used for calculation,

$$N = \frac{z_{1-\alpha/2}^2 \times p\,(1-p)}{d^2}$$ where, N is sample size, p = 10.22%, d = 5 & α = 0.05.

$$N = \frac{(1.96)^2 \times 10.22\,(100-10.22)}{5^2} = 141$$

Calculated sample size came to be 141, after taking 10% of non compliance rate, sample size was rounded off to 155.

Inclusion Criteria:

1. People with known history of type 2 diabetes mellitus aged between 30-65 years.

2. People residing in Urban Field Practice Area of Shri BM Patil Medical College, for a minimum period of one year.

Exclusion Criteria:

1. Diabetics patients aged < 30 years and > 65 years.

2. Gestational DM and Type -1 Diabetes Mellitus patients.

3. Those who are not willing to participate in study.

INTERVIEW

After obtaining ethical clearance from the Institutional ethical committee, the study was carried out in the urban field practice area of Shri B. M. Patil Medical College Hospital & Research Centre.

The purpose and nature of the study was explained to the participants, and were informed that their participation was entirely voluntary, their anonymity would be assured, they could withdraw from the study at any 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.

A total of 1260 houses were accessed by house to house survey in the urban field practice area catering a population of 10000, to enumerate all the known type 2 diabetics in the age group of 30 – 65 yrs residing in the Urban field practice area.

Participants who fulfilled the inclusion criteria were then interviewed using a World health Organization Quality of Life – BREF (WHOQOL – BREF) scale to elicit the quality of life; PHQ-9 to assess the depression; and pretested questionnaire to elicit the socio-demographic and behavioral profile. If the participants were not available at the time of visit or if houses were locked, then those houses were visited on three consecutive days to include the eligible participants in the study.

Height and Waist circumference was measured by using non stretchable measuring tape to the nearest of 0.1cm. Weight was recorded using a standardised Bathroom weighing scale to the nearest of 0.1kg. Body mass index was then calculated. Two reading of Blood pressure was recorded 5 minutes apart using a mercury sphygmomanometer on right arm in sitting posture. Average of two readings was used for analysis. Blood HbA1c levels were measured by using HbA1c Now Single use Kit. This measurement was used in our study as, many studies like Diabetes Complications and Control Trial (DCCT) and the United Kingdom Prospective Diabetes Study measured HbA1c and related this clinical outcome of glycemic control to the complications of diabetes[58,59]. The American Diabetes Association (ADA) also recommends that HbA1c should be measured at least twice a year in persons with diabetes[60].

Instruments Used For Data Collection

All the physical instruments used for data collection were regularly checked for validity and reliability throughout the period of data collection. Standard procedures were followed to minimize the errors due to use of these measuring tools.

1. **Measuring Tape:** Calibrated measuring tape marked in centimeters was used for measuring height and waist circumference.

   a. **Height Measurement:**

   Height measurement was taken in erect standing position bare foot with both the feet together, heels against the walls and looking straight ahead. Height and Waist circumference was measured by using non stretchable measuring tape to the nearest of 0.1cm.

   b. **Waist circumference Measurement:**

   It was measured by asking the subject to stand in erect posture and placing the tape horizontally around the waist with the upper border of tape touching the lower margin of umbilicus.

   The subject was asked to take in a normal inspiration and normal expiration, the waist circumference was recorded in normal expiration. Waist circumference was measured by using non stretchable measuring tape to the nearest of 0.1cm. Waist circumference above 90 cm in males and 80 cm in females was considered as abnormal[61].

2. **Weighing Machine:** Bathroom Portable weighing scale calibrated at 0.5 kg marked from 0-130 kg's was used.

    a. **Weight Measurement:**

    Study subjects were measured for their weight to the nearest 0.1 kg using a standard portable Bathroom weighing machine without wearing a foot wear. The weighing machine was calibrated every week to the standard weights and necessary adjustments were made. Weight was recorded using a standardized Bathroom weighing scale to the nearest of 0.1kg.

3. **Sphygmomanometer and stethoscope:** was used to measure blood pressure of study participants.

    Blood pressure (BP) measurements:

    Blood pressure was measured using sphygmomanometer, first by palpatory method followed by auscultatory method. Two such reading was recorded at an interval of at least 3 minutes and the mean value was recorded. Hypertension was diagnosed using criteria systolic blood pressure ≥ 140 mmHg and /or diastolic blood pressure ≥ 90mmHg. The subjects who self reported and had been on antihypertensive medication were also considered as hypertensive.

4. **HbA1c Single use kit**: A1C Now$^+$ from PTS Diagnostics was used for measurement of blood glucose levels.

    Blood glucose measurement: The adequacy of glycemic control in diabetes mellitus is a keystone in reducing morbidity and mortality of the disease. HbA1c level to be done every 3 months, as this test measures the recent average blood sugar (glucose) control. Hence, fasting on the day of the test is not required. This test measures % of glycated Hb which is formed depending on the average glucose concentration in the plasma over 3 months. HbA1c is formed by nonenzymatic glycation pathway by exposure of Hb to plasma glucose.[62]

5. **Steps in measurement of HbA1C levels:**

    Step 1: participant was explained about the procedure and informed consent was taken from them.

    Step 2: index finger of right hand was used to draw sample, hence it was wiped with spirited cotton and dried.

    Step 3: using a single use lancet, a small prick is made on the right hand index finger; first drop of blood is wiped with clean cotton.

    Step 4: second drop of blood is taken in the sample dilution kit of A1C Now$^+$

    Step 5: blood is now mixed with dilution fluid by shaking the dilution kit 3-4 times, in up – down motion.

    Step 6: testing cartridge is opened and it is attached to the A1C Now$^+$ testing device.

    Step 7: now diluted blood in the dilution kit is attached to the cartridge and wait for 10 -15 minutes to obtain the result.

6. **HbA1C levels diagnosis of Type 2 DM:** HbA1c can indicate people with pre-diabetes or diabetes. The target level for diabetes patients is to maintain HbA1C at $\leq 6.5\%$.

7. **WHOQOL BREF Instrument:**[63]

The WHOQOL BREF was constructed by 1995. It contains total of 26 questions. It consists of four domains namely – physical, psychological, social and environmental. Each domain consists of 7, 6, 3 and 8 questions respectively. There are also two items, namely- Q1 is about an individual's overall perception of quality of life and Q2 is about his or her perception of overall health.

The instrument places primary importance on the perception of the individual and provides a new prospective on the disease by focusing on the individual's own view of their well being.

The facets incorporated within the domain are:

Physical Health: Energy and fatigue, pain and discomfort, sleep and rest.

Psychological: Bodily image and appearance, negative feelings, positive feelings, self esteem, thinking, learning, memory and concentration.

Social Relationship: Personal relationship, social support and sexual activity.

Environment: Financial resources, freedom, physical safety and security, health and social care, accessibility and quality, home, environment, opportunities for acquiring new information and skill,

participation in and opportunities for reactional/leisure, physical environment (population/noise/traffic/climate), transport.

The domain scores are scaled in positive direction, where higher scores denote higher quality of life. The WHOQOL BREF is easy to administer and has been validated.

Method of Manual Calculation:

Physical domain: $[(6-Q3)+(6-Q4)+Q10+Q15+Q16+Q17+Q18]/7$

Psychosocial domain: $[(Q5+Q6+Q7+Q11+Q19+(6-Q26)]/6$

Social domain: $[Q20+Q21+Q22]/3$

Environmental domain: $[Q8+Q9+Q12+Q13+Q14+Q23+Q24+Q25]/8$

The responses for Q1 and Q2, namely the subject's perception of their own quality of life and their perception regarding their overall health were noted separately.

Where more than 20% data were missing, the assessment was discarded. Where up to 2 items were missing from domain was not calculated.

8. **PHQ – 9 (Physical Health Questionnaire – 9):[64]**

In this study PHQ-9, i.e., Physical Health Questionnaire with 9 items was used to assess the mental status of the study participants. The PHQ-9 is a multipurpose instrument used for screening, diagnosing, monitoring and measuring the severity of depression. The PHQ-9 incorporates DSM IV depression diagnostic criteria with other leading major depressive symptoms into a brief self-report tool.

Scoring and assessment guidelines of PHQ-9:[64]

Score	Recommended Actions
0-4	Normal range or full remission. The score suggests the patient may not need depression treatment.
5-9	Minimal depressive symptoms. Support, educate, call if worse, return in 1 month.
10-14	Major depression, mild severity. Use clinical judgment about treatment, based on patient's duration of symptoms and functional impairment. Treat with antidepressant or psychotherapy.
15-19	Major depression, moderate severity. Warrants treatment for depression, using antidepressant, psychotherapy or a combination of treatment.
20 or higher	Major depression, severe severity. Warrants treatment with antidepressant and psychotherapy, especially if not improved on monotherapy; follow frequently.

Definitions of the study variables

❖ **Age :** Age was recorded in completed years as revealed by the subjects and also as seen in Adhaar Card or Voters ID.

❖ **Type of family:[66]**

➕ 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 live 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 :[66]**

➕ **No formal schooling / illiterate:** Is defined as the person who could neither read nor write in any language.

- **Primary Schooling:** A person who has studied till or less than 7th standard.

- **High Schooling:** The person who had studied from 8th to 10th standard.

- **Pre university schooling:** The person who attended college ($\leq$ PUC 2) and /or studied the diploma degree.

- **Graduate:** The person who completed bachelor degree.

❖ **Occupation:**[67]

- homemaker: involved only in household chores.

- Self employed: small businessman, shopkeeper, domestic servant.

- Private employee: Factory worker, labourer, Salesman etc

- Government employee: Clerk, typist, teachers etc

❖ **Socio-Economic status:**[69]

- Self- reported monthly income was recorded and per capita income was calculated. Modified BG Prasad's classification was used to assess the social class of the study subjects.

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

  $= 277 / 100 = 2.77$

- 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:

Socio-economic class	B.G.Prasad's classification(1961)	Modified B G Prasad classification(2016)
Upper	Rs 100 & above X MF	6261 & above
Upper middle	Rs 99- 50 X MF	3099-6260
Lower middle	Rs 49-30 X MF	1835-3098
Upper lower	Rs 29-15 X MF	949-1834
Lower	Rs<15 X MF	Below 948

❖ **Physical activity:[66]**

⬥ Sedentary: it represents any activities like watching TV, reading, sleeping, working at a computer, office work, shop owner, retired person, talking with friends etc.

⬥ Moderate physical activity: it includes brisk walking, regular cycling either for house-hold or for recreational purpose, scrubbing the floors etc. e.g.: drivers, conductors and artisians.

⬥ Vigorous physical activity: Regular jogging, or running, cycling> 10 miles/ hr, walking with load uphill, manual digging \, etc or any such activities which require severe physical excretion. Eg farming coolie, carpenters, and house maids.

❖ **Tobacco consumption:[69]**

All the study subjects were asked regarding the history of tobacco consumption in any form; smoking tobacco such as beedi, cigarette etc. the information included the frequency, duration of consumption, and also whether they left the habit or not. Depending upon their tobacco consumption patterns, the subjects were grouped into any one of the following groups.

Smoking tobacco consumption:

Non-smoker: is defined as a person who has never smoked tobacco, or smoked <100 cigraratters / beedis in his life time.

Ex-smoker: is defined as person who has smoked > 100 cigarettes / beedi in his lifetime and is not smoking since last one year.

Current smoker: A person who had smoked > 100 cigaretters / beedi in his life time and is still smoking.

❖ Alcohol Consumption:[70]

Detailed history of alcohol consumption habit was collected, like consumption of beer, brandy, whisky, etc and the subjects were grouped as follows.

- Non-user; A person who never consumed alcohol

- Ex-user: a person who was consuming alcohol, but left the habit on year back and currently not consuming.

- Current user: A person who consumes alcohol at present.

❖ Body Mass Index (BMI): [71]

BMI was calculated using the formula,

$$\text{BMI} = \frac{weight\ in\ Kg}{(height\ in\ mts)^2}$$

Body mass index (kg/m^2)	Classification
18- 23	Normal
23- 25	Overweight
25-28.5	Class I obesity
28.5 – 32.5	Class II obesity
32.5 – 37.5	Class III obesity

❖ **Family history of diabetes mellitus**

+ If the study participant gave history of DM in his / her blood relatives, which includes first degree relatives such as father, mother, brother or sister.

❖ **Eating Habits:**

+ Vegetarians: if the study participants gave history of consumption of foods that come from plants, like grains, fruits, vegetables, and nuts were included as vegetarians.

+ Mixed: if the study participants gave history of consumption of animal origin foods along with plant origin were included under mixed diet.

Statistical analysis:

The Data was complied in Microsoft (MS) Excel sheet and analyzed using SPSS (Statistical Package for Social Sciences) software version 16.0.

Results were subjected to following statistical analysis. All characteristics were summarized descriptively. For continuous variables, the summary statistics of N, mean, standard deviation about the arithmetic mean (SD) were used. For categorical variables, the number and percentage were used in data summarization.

Chi square test (χ^2) or Freeman-Halton Fisher exact test was employed to determine the significance of associations between variables for categorical data. If p value was >0.05, then the results were considered to be non significant and if p value was <0.05, then the results were considered to be statistically significant.

Linear regression analysis was used to see the adjusted effect of independent variables on the dependent variables.

Table 01: Socio - demographic profile of study population

Background variables		N	%
Age (yrs)	30-40	58	36.7
	41-50	36	22.8
	51-60	42	26.6
	>60	22	13.9
Sex	Male	63	39.9
	Female	95	60.1
Marital status	Married	142	89.9
	Unmarried	2	1.3
	Widow/widower/separated	14	8.9
Religion	Hindu	105	66.5
	Muslim	53	33.5
Education	No formal education	58	36.7
	Primary school	56	35.4
	High school	34	21.5
	Pre university	10	6.3
Occupation	Government	50	31.6
	Private	51	32.3
	Self employed	36	22.8
	Home maker	21	13.3
SES	I (>6528)	2	1.3
	II (3264 - 6527)	17	10.8
	III (1959 - 3263)	35	22.2
	IV (979 - 1958)	56	35.4
	V (<978)	48	30.4
Type of family	Nuclear	71	44.9
	Joint	55	34.8
	Extended	32	20.3
Total		158	100

158 people suffering from type 2 diabetes mellitus participated in the study. A majority of 36.7% of the participants belonged to age group of $30 - 40$ yrs, followed by 26.6% belonging to age group of $51 - 60$ yrs. Gender distribution of the study participants showed that 60.1% were females and 39.9% were males. Distribution of marital status revealed that a majority of 89.9% were married, 8.9% were either widow, widower or separated and 1.3% were unmarried. 66.5% belonged to Hindu religion and remaining 33.5% belonged to Muslim religion. Distribution of study population as per their education showed that, majority of 36.7% never had any formal schooling, followed by 35.4% who had only primary schooling. More than ≈ 66% of the study participants were in Class IV and V of Modified B. G. Prasad Classification. In our study 44.9% of the participants resided in nuclear family, followed by 34.8% in joint family and 20.3% in three generation family.

Table 02: Genderwise distribution and differences of some Risk factors in the study population

Risk Factors		Male (N=63)		Female (N=95)		Total (N=158)		p value
		N	%	N	%	N	%	
Tobacco smoking	Current user	6	9.5	3	3.2	9	5.7	0.249
	Ex user	5	7.9	7	7.4	12	7.6	
	Total	**11**	**17.5**	**10**	**10.5**	**21**	**13.3**	
Tobacco chewing	Current user	9	14.3	9	9.5	18	11.4	0.391
	Ex user	2	3.2	1	1.1	3	1.9	
	Total	**11**	**17.5**	**10**	**10.5**	**21**	**13.3**	
Alcohol consumption	Current user	6	9.5	4	4.2	10	6.3	**0.013 ***
	Ex user	4	6.3	0	0.0	4	2.5	
	Total	**10**	**15.9**	**4**	**4.2**	**14**	**8.9**	
Dietary habit	Vegetarian diet	32	50.8	43	45.3	75	47.5	**0.031 ***
	Mixed diet	31	37.3	52	62.7	83	52.5	
Outside food/snacks consumption per week	Daily	3	4.8	18	18.9	21	13.3	**0.053 ***
	Thrice a week	39	61.9	40	42.1	79	50.0	
	Twice a week	16	25.4	28	29.5	44	27.8	
	Once a week	5	7.9	9	9.5	14	8.9	
Type of work	Heavy worker	20	31.7	28	29.5	48	30.4	0.457
	Moderate worker	35	55.6	60	63.2	95	60.1	
	Sedentary worker	8	12.7	7	7.4	15	9.5	
Family history of DM		7	11.1	7	7.4	14	8.9	1.000
BMI	Underweight	3	27.3	8	72.7	11	6.9	0.303
	Normal	20	34.5	38	65.5	28	17.7	
	Overweight	40	44.9	49	55.1	89	56.3	
Abdominal Obesity	Yes	16	34.0	31	66.0	47	29.7	0.948
	No	47	42.3	64	57.7	111	70.2	

Note: *siginificant at 5% level of significance (p<0.05)

The above table shows the distribution of of some known risk factors of type-2 diabetes among male and female study population. Among alcohol consumers, 9.5% and 6.3% of males were current and ex-users respectively and only 4.2% of females reported as alcohol users, this difference was statistically significant at $p < 0.05$. There was no statistical significance in difference of tobacco consumption among males and females. 50.8% of vegetarians were males whereas 45.3% of them were females. Among mixed diet consumers, 37.3% were males whereas 62.7% were females. The difference in the observations of dietary pattern was statistically significant at $p < 0.05$. Outside food or snacks consumption showed that, 18.9% of females consumed daily while only 4.8% of males did so. But, at least 3 time consumption of outside snacks per week was seen to be around 62% in male participants and only 42.1% in female participants. Overall there was an association between gender and eating outside food / snacks.

Figure 01: Distribution of selected Co - morbidities in study population.
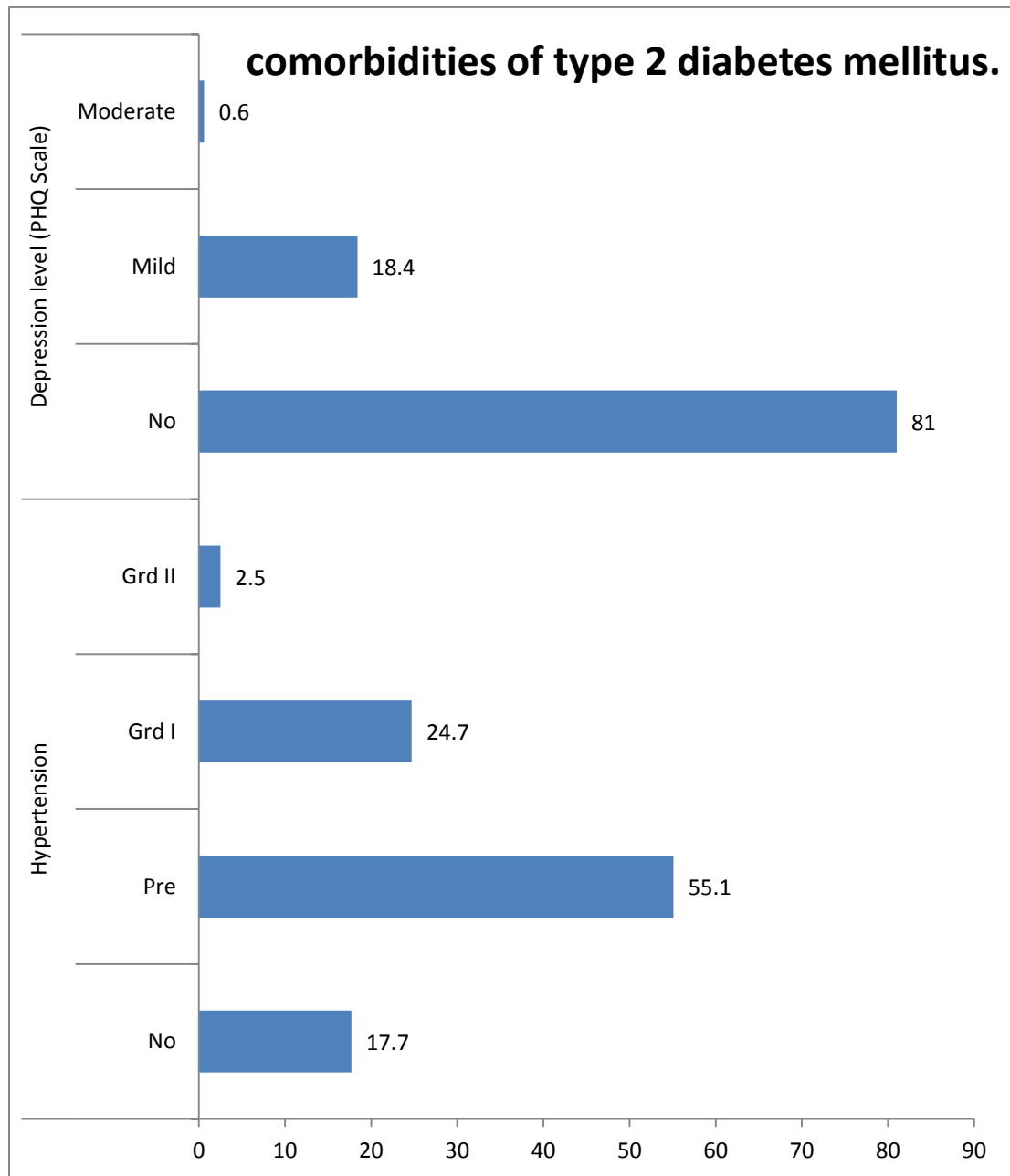
Results show that 24.7% and 2.5% of the known type 2 diabetics were having grade I and grade II hypertension respectively. 55.1% were having pre – hypertension. After application of PHQ – 9 item scales for diagnosis of depression, 18.4% had mild depression, 0.6% had moderate depression.

Table 03: Glycemic control (HbA1C levels) v/s selected risk factors of type 2 DM.

Selected risk factors		Excellent (4.5-6.4) (N=13)		Good (6.5-7.0) (N=57)		Acceptable (7.1-8.0) (N=69)		Poor (>8.0) (N=19)		Total (N=158)	p value
		N	%	N	%	N	%	N	%	N	
Gender	**Male**	5	7.9	19	30.1	26	41.3	13	20.7	63	**0.037***
	Female	8	8.4	38	40.0	43	45.3	6	6.3	95	
BMI	**Under weight**	3	21.4	8	57.1	2	14.3	1	7.2	14	**0.013***
	Normal	3	5.4	15	26.7	30	35.1	8	14.2	56	
	Over weight/ obese	7	7.9	34	38.6	37	42.1	10	11.4	88	
Type of work	**Heavy**	7	14.7	13	27.1	22	45.8	6	12.5	48	0.348
	Moderate	4	4.2	38	40.0	42	44.2	11	11.6	95	
	Sedentary	2	13.3	6	40.0	5	33.3	2	13.4	15	

Note: *siginificant at 5% level of significance (p<0.05)

40% of female participants had HbA1C levels in range of 6.5-7.0%, whereas majority of 41.3% of males had their HbA1C levels in range of 7.1-8.0%, which is beyond the target level for diabetic patients (HbA1C at ≤6.5). This was found to be statistically significant at p<0.05. 21.4% of participants with underweight had maintained their HbA1C levels ≤6.5%, whereas around 53.5% of overweight or obese participants had their HbA1C levels ≥7.0% and 38.6% had HbA1c level 6.5 − 7.0%. This finding was also found to be statistically significant at p<0.05.

Figure 02: Treatment modalities used v/s HbA1C levels.
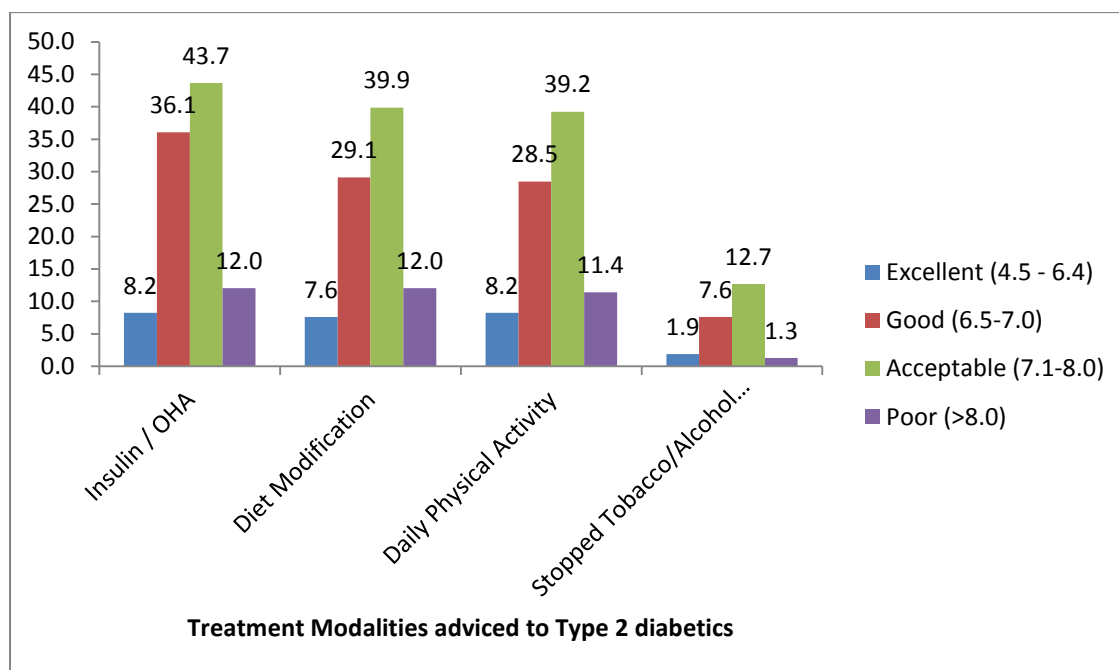
* Multiple answers were elicited.

The above figure shows that, majority of 43.7% of participants on insulin or oral hypoglycemic agents had their HbA1c levels in the range of 7.1-8.0%, followed by 36.1% & 8.2% maintained it in range of 6.5-7% and 4.5-6.4% respectively. 29.1% & 7.6% of those participants who had dietary modifications along with drug therapy, had their HbA1c levels in the range of 6.5-7.0% , 4.5-6.4% respectively. Among the participants who were practicing daily physical activity and tobacco / alcohol cessation along with drug therapy, majority of 39.2% and 12.7% had their HbA1c levels at 7.1-8.0% respectively.

Table 04: Glycemic Control (HbA1C levels) v/s usage of Alternate system of medicine. (AYUSH)

Selected risk factors		Excellent (4.5-6.4) (N=13)		Good (6.5-7.0) (N=57)		Acceptable (7.1-8.0) (N=69)		Poor (>8.0) (N=19)		Total (N= 158)	p value
		N	%	N	%	N	%	N	%	N	
Usage of alternate system of medicine for management	Yes	1	2.1	2	4.2	35	72.9	10	20.8	48	**<0.01***
	No	12	10.9	55	50.0	34	30.9	19	17.2	110	

Note: *siginificant at 5% level of significance (p<0.05)

Among the participants who use Alternate system of medicine for treatment of type 2 DM, we found that ≈73% and ≈21% had their glycemic levels poor at 7.1-8.0 and >8.0% respectively. This finding was statistically significant at 5% level of significance.

Table 05: Type of diabetic complications diagnosed by physician in past 1 year v/s blood glycemic levels (HbA1c).

Complications	Excellent (4.5-6.4) N=13 (%)	Good (6.5-7.0) N=57 (%)	Acceptable (7.1-8.0) N=69 (%)	Poor (>8.0) N=19 (%)	p value
Hypoglycemia	4 (30.7)	30 (52.6)	33 (47.8)	12 (63.1)	0.424
Retinopathy	Nil	1 (1.7)	1 (1.4)	5 (26.3)	**0.0005***
Nephropathy	Nil	Nil	1 (1.4)	2 (10.5)	0.089
Neuropathy	1 (7.7)	3 (5.2)	7 (10.1)	9 (47.3)	**<0.001***
Foot Ulcers	Nil	Nil	1 (1.4)	4 (21.0)	**0.001***
Angina	1 (7.7)	1 (1.7)	2 (2.9)	Nil	0.398
Urinary Tract Infection	Nil	7 (12.3)	8 (11.6)	17 (89.4)	**<0.001***

*Multiple answers were elicited.

Among the participants with HbA1c levels $\geq$ 8.0%, 89.4% had UTI, 47.3% had neuropathy, 21% had foot ulcers and 26.3% had retinopathy. There was statistically significant association between HbA1c poor control level and majority of the complications suffered by Study participants

Results of Quality of Life measurement scores and associated factors of study population

Table 06: Distribution of Domains of Quality of life scores (WHOQOL BREF) among the study participants.

Quality of life Domain	Raw score			Transformed Score (0-100)		
	Min	Max	Mean ± SD	Min	Max	Mean ± SD
Physical health	13	28	21.1 ± 3.2	21.4	75.0	50.5 ± 11.5
Psychological	10	22	17.3 ± 2.6	16.7	66.7	47.1 ± 10.8
Social relationships	3	12	8.2 ± 2.0	0.0	75.0	45.8 ± 16.1
Environment	18	32	24.0 ± 2.8	31.3	75.0	50.0 ± 8.8

The above table represents the scores of WHOQOL – BREF scale on 0 – 100 scale (i.e., transformed scores). Mean score in physical health domain was around 50.5, similarly for psychological, social and environmental domains it was 47.1, ≈48 and 50.0 respectively.

Figure 03: Distribution of Quality of life scores among the study population –
Domain Categories.
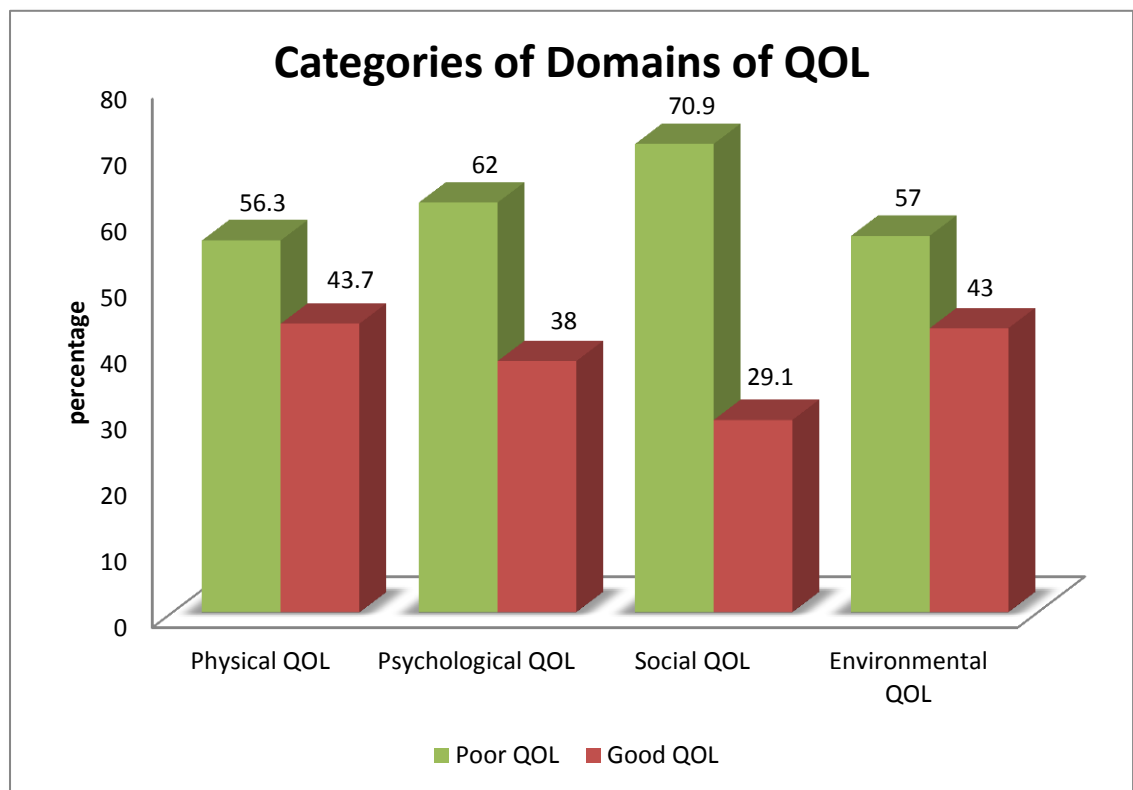
In our study, majority of 56.3% had poor physical QOL, 62% had poor psychological QOL, around ≈71% of the study participants had poor social QOL and 57% had poor environmental QOL and only 43% having good environmental QOL.

Table 07: Distribution of Physical relationships domain of Quality of life scores with selected Socio Demographic Variables

Selected Socio Economic Variables		Poor		Good		χ2 p value(2 sided)
		N	%	N	%	
Age (Yrs)	30-40	34	58.6	24	41.4	0.038*
	41-50	17	47.2	19	52.8	
	51-60	20	47.6	22	52.4	
	>60	18	81.8	4	18.2	
Sex	Male	40	63.5	23	36.5	0.139
	Female	49	51.6	46	48.4	
Occupation	Government	29	58.0	21	42.0	0.545
	Private	25	49.0	26	51.0	
	Self Employed	21	58.3	15	41.7	
	Home Maker	14	66.7	7	33.3	
SES	I (>6528)	Nil	-	2	100.0	0.115
	II (3264 - 6527)	12	70.6	5	29.4	
	III (1959 - 3263)	15	42.9	20	57.1	
	IV (979 - 1958)	35	62.5	21	37.5	
	V (<978)	27	56.3	21	43.8	

Note: *siginificant at 5% level of significance (p<0.05)

The above table describes the distribution of categories of physical QOL with socio demographic variables. Majority of ≈ 82% of the study participants of 60yrs and older had poor physical QOL, when compared to younger age group where, only 58.6% and 47.2% in the age of 30 – 40 yr old and 41 – 50yr old respectively had poor physical QOL. This difference was statistically significant at 5% level of significance (p<0.05).

Table 08: Distribution of Physical relationships domain of Quality of life scores with selected DM Risk factors

Selected DM Risk factors		Poor		Good		χ2 p value(2 sided)
		N	%	N	%	
BMI	Underweight	4	36.4	7	63.6	**0.05**[*]
	Normal	39	67.2	19	32.8	
	Overweight/Obese	46	51.7	43	48.3	
Hypertension	No	17	60.7	11	39.3	0.768
	Pre	46	52.9	41	47.1	
	Grade I	24	61.5	15	38.5	
	Grade II	2	50.0	2	50.0	
Depression level (PHQ 9 Scale)	No	77	60.2	51	39.8	0.096
	Mild	12	41.4	17	58.6	
	Moderate	Nil	-	1	100.0	
Abdominal obesity	No	65	58.6	46	41.4	0.385
	Yes	24	51.1	23	48.9	

Note: *siginificant at 5% level of significance (p<0.05)

The above table describes the distribution of physical QOL with some co – morbid conditions like obesity (BMI), hypertension, depression, HbA1C levels and abdominal obesity.

Majority of 67.2% of normal BMI study participants had poor physical QOL, compared to 36.4% and 51.7% of underweight and overweight/obese participants respectively who had poor physical QOL. There was statistical association between BMI and physical QOL at 5% level of significance (p<0.05).

Table 09: Distribution of Psychological relationships domain of Quality of life scores with selected Socio demographic Variables

Selected Socio demographic Variables		Poor		Good		χ2 p value(2 sided)
		N	%	N	%	
Sex	Male	40	63.5	23	36.5	0.757
	Female	58	61.1	37	38.9	
Marital status	Married	88	62.0	54	38.0	0.505
	Unmarried/Widow/ Widower/Separated	10	62.5	6	37.5	
SES	I (>6528)	2	100.0	Nil	-	**0.05***
	II (3264 - 6527)	12	70.6	5	29.4	
	III (1959 - 3263)	17	48.6	18	51.4	
	IV (979 - 1958)	31	55.4	25	44.6	
	V (<978)	36	75.0	12	25.0	

Note: *siginificant at 5% level of significance (p<0.05)

The above table shows the distribution of categories of psychological QOL domain with selected Socio Demographic Variables. There was no gender associated difference in psychological QOL domain. Majority of 75% of study population belonging to Class V SES according to Modified B. G. Prasad classification had poor psychological QOL, which followed by Class IV, II & III respectively. The association of SES with psychological QOL was statistically significant at p<0.05.

Table 10: Distribution of Psychological relationships domain of Quality of life scores with type of work

Type of work	Poor		Good		χ2 p value(2 sided)
	N	%	N	%	
Heavy Worker	33	68.8	15	31.3	
Moderate Worker	61	64.2	34	35.8	**0.011***
Sedentary Worker	4	26.7	11	73.3	

Note: *siginificant at 5% level of significance (p<0.05)

The above table and graph shows the distribution type of work with psychological QOL, majority of ≈ 69% of heavy worker had poor psychological QOL, followed by moderate worker with 64.2%. This was statistically significant at p<0.05.

Table 11: Distribution of social relationships domain of Quality of life scores with selected Socio demographic Variables

Selected Socio Demographic Variables		Poor		Good		χ2 p value(2 sided)
		N	%	N	%	
Sex	Male	47	74.6	16	25.4	0.402
	Female	65	68.4	30	31.6	
Marital status	Married	102	71.8	40	28.2	0.436
	Unmarried/Widow/ Widower/Separated	10	62.5	6	37.5	
SES	I (>6528) & II (3264 - 6527)	15	79.0	4	21.0	0.277
	III (1959 - 3263)	21	60.0	14	40.0	
	IV (979 - 1958)	44	78.6	12	21.4	
	V (<978)	32	66.7	16	33.3	

Note: *siginificant at 5% level of significance (p<0.05)

Majority of ≈ 75% of males in our study had reported poor social QOL than females. 71.8% of married participants had poor social QOL. It was seen that, increase in SES was directly proportional to the increase in percentage of participants in poor Social QOL domain.

Table 12: Distribution of Social relationships domain of Quality of life scores with selected DM risk factors

Selected DM Risk factors		Poor		Good		χ2 p value(2 sided)
		N	%	N	%	
BMI	Underweight	7	63.6	4	36.4	0.841
	Normal	42	72.4	16	27.6	
	Overweight/Obese	63	70.8	26	29.2	
Hypertension	No	18	64.3	10	35.7	0.34
	Pre	60	69.0	27	31.0	
	Hypertension (Grade I & II)	34	79.0	9	21.0	
Depression level (PHQ Scale)	No	89	69.5	39	30.5	0.43
	Depression (Mild & Moderate)	23	76.6	7	23.3	
Abdominal obesity	No	76	68.5	35	31.5	0.304
	Yes	36	76.6	11	23.4	

Note: *siginificant at 5% level of significance (p<0.05)

A majority of ≈ 71% of overweight and obese participants reported poor social QOL life domain. Majority of 79% of hypertensive (either grade I & II) have poor social QOL, followed by pre hypertensive with 69% and then 64.3% of participants with no hypertension.76.6% of the depressed patient (either mild or moderate) according to PHQ-9 scale reported poor social QOL. Among abdominal obese participants 76.6% reported poor social QOL.

Table 13: Distribution of Environmental domain of Quality of life scores with selected Socio Demographic

Selected Socio Demographic Variables		Poor		Good		χ2 p value(2 sided)
		N	%	N	%	
Sex	Male	32	50.8	31	49.2	0.202
	Female	58	61.1	37	38.9	
Marital status	Married	77	54.2	65	45.8	**0.03**[*]
	Unmarried/Widow/ Widower/Separated	13	81.2	3	18.8	
Occupation	Government	28	56.0	22	44.0	0.21
	Private	25	49.0	26	51.0	
	Self Employed	21	58.3	15	41.7	
	Home Maker	16	76.2	5	23.8	

Note: *siginificant at 5% level of significance (p<0.05)

Distribution of environmental QOL with gender of the study participants revealed that, majority of females with 61.1% had poor environmental domain than males. Majority 81.2% of unmarried /widowed/ separated had poor environmental QOL domain scores , when compared to married. This was statistically significant at 5% level of significance (p<0.05). Majority of 76.2% of homemakers/ not employed had poor environmental domain scores of QOL, when compared to employed.

Table 14: Distribution of Environmental domain of Quality of life scores with selected DM risk Factors

Selected DM risk Factors		Poor		Good		χ2 p value(2 sided)
		N	%	N	%	
BMI	Underweight	4	36.4	7	63.6	0.342
	Normal	33	56.9	25	43.1	
	Overweight/Obese	53	59.6	36	40.4	
Hypertension	No	13	46.4	15	53.6	0.088
	Pre Hypertension	48	55.2	39	44.8	
	Hypertension (Grade I & II)	29	67.4	14	32.6	
Depression level (PHQ Scale)	No	77	60.2	51	39.8	0.09
	Depression (Mild or Moderate)	13	43.3	17	56.7	
Abdominal obesity	No	57	51.4	54	48.6	**0.029***
	Yes	33	70.2	14	29.8	

Note: *siginificant at 5% level of significance (p<0.05)

Environmental QOL was found to be poor in 70.2% of the participants with abdominal obesity, and only 51.4% poor in participants with no abdominal obesity. This was found to statistically significant at 5% level of significance (p<0.05).

Table 15: Distribution of Perceived Quality of life among male and female study participants.

Quality of life		Male (N=63)		Female (N=95)		Total (N=158)		p value
		N	%	N	%	N	%	
How would you rate your quality of life?	Poor	19	30.1	36	37.9	55	34.8	0.123
	Neither poor nor good	30	47.6	30	31.6	60	38.0	
	Good	14	22.2	29	30.5	43	27.2	
How satisfied are you with your health?	Poor	21	33.3	37	38.9	58	36.7	0.102
	Neither poor nor good	32	50.8	33	34.7	65	41.1	
	Good	10	15.9	25	26.3	35	22.2	

Note: *siginificant at 5% level of significance (p<0.05)

The above table represents the distribution of perceived QOL among male and female participants; majority of 47.6% of male participants rated their QOL as neither poor nor good, whereas majority of ≈ 38% of female participants rated it as poor QOL.

Regarding satisfaction with health condition; majority of male participants with ≈ 51% rated it as neither poor nor good, whereas majority of female participants with ≈ 39% rated it as poor.

Table 16: Linear Regression Analysis of Predictors of perceived QOL

Predictors		B	p value
(Constant)		1.674	0.448
Physical health QOL		0.003	0.713
Psychological health QOL		-0.015	0.070
Social relationships QOL		-0.001	0.925
Environmental QOL		0.027	**0.005***
Depression	No (ref)		
	Mild	-1.478	**<0.001***
	Moderate	-2.147	**0.033***
Hypertension	No (ref)		
	Pre	0.036	0.912
	GrI	0.153	0.780
	GrII	-0.444	0.632
Blood pressure (SBP) (mmHg)		-0.012	0.395
Blood pressure (DBP) (mmHg		0.021	0.073
HbA1c level		-0.014	0.915
Waist circumference (cm)		0.005	0.480
Body Mass Index (Kg/m2)		0.008	0.504
Age (Yrs)		-0.005	0.542
Sex	Male (ref)		
	Female	0.147	0.405
Marital status	Married (ref)		
	Unmarried	-0.583	0.449
	Widow/Widower/Separated	-0.078	0.795
Religion	Muslim (ref)		
	Hindu	0.075	0.684

Note: *siginificant at 5% level of significance (p<0.05)

Poor scores of environmental QOL domain, mild and moderate depression was found to be statistically associated with poor outcome of perceived QOL.

DISCUSSION

Few Epidemiological studies are done on Quality of Life among known type 2 diabetes patients in urban slum community in Indian context. . They lack uniformity in measuring QOL score in physical, psychological, social and environmental domains, resulting in non – comparability of their QOL scores, both at national and international levels.

Although type 2 diabetes is known to be a serious burden in Indian scenario, there are still quite scarce studies that assess the impact of diabetes on the patients' QOL. It is very important for medical and clinical disciplines to examine the quality of life and find opportunities to improve it.

This study examined the relationship of demographic factors and risk factors and blood glycemic levels with QOL of the study participants.

Socio – demographic factors of study participants:

Age:

In our study the mean age was 47.6±10.7yr and participants were maximum in the age group of 30-40yrs with ≈ 37%, which was followed by age groups 51-60yr, 41-50yr and >60yr with 26.6%, 22.8% and 13.9% respectively. In a screening study conducted at Urban Health Training Center, by Domple VK *et al*. in Nanded, Maharashtra reported higher prevalence of type 2 diabetes mellitus of 30% among younger age group of 30-40yrs old, which is similar to our findings[71]. Previous studies by Dhadwal *et al*[73], Patadin *et al*[74] and Zargar *et al*[75] etc. showed the higher prevalence of type 2 diabetes among population with 40yrs and above. Previously, it was thought to be a disease of middle-aged and older people but in recent years, the

age of onset has reduced and type 2 diabetes is being reported in younger age group worldwide, particularly in high prevalence populations like India[76]. This overall rise in global prevalence of type 2 diabetes, among younger population can be attributed to factors like sedentary life style, behavioral risk factors such as smoking and alcoholism etc.[76] But population-based data in this regard are sparse in India. One such multi-centric study by ICMR-INDIAB in 2011, reported that prevalence of type 2 diabetes was increasing among 25–34 years age group with a decline after age 65yrs. They attributed this decrease in prevalence of diabetes after 65 years as possibly due to survivor bias, reflecting deaths at earlier ages due to complications of diabetes[78].

Gender:

In our study female participants with type 2 diabetes were 60.1%, whereas male participants with type 2 diabetes were 39.9%. Gender distribution from community studies in India has shown inconsistent results. A study from North India by Mishra A *et al.*[78] showed female preponderance while other study from southern India by Ramachandran A *et al.*[79], reported higher prevalence in males and some other studies have found no gender difference in prevalence[80]. Generally females suffer from low reporting especially in hospital based studies as they lack decision making to acess care and family support[81]. But since our study was a community based house to house survey we could include more female study participants, who otherwise could have been missed, this might also explain female majority in our study

Education:

Level of education may have impact on health outcome, QOL and adherence to treatment. In our study, 36.5% of study participants had no formal education and 35.4% had attended schooling only up to primary. This is comparable to another community based study conducted at urban slums of Mumbai, by Mahajan HD *et al.*[82], where 27% of known diabetics were illiterate and 41% of them attended schooling only up to primary. On the contrary, some hospital based studies like the study conducted by Jain V *et al.*[83] at Sevagram, Wardha, among type 2 diabetics showed that only 4% were illiterate and while 16% were with Post graduation . Linear regression analysis in our study did not show the educational level as predictor or associated factor with perceived QOL .

Socio economic status:

In our study maximum 35.4% of the participants belonged to class IV SocioEconomic Strata according to modified B G Prasad Classification, this was followed by 30.4% belonging to class V, 22.2% to class III, 10.8% to class II and only 1.3% to class I. This was similar to the findings of another study done on known diabetic population in urban field practice area where 42% of them were belonging to Class IV SES[72]. On the contrary some studies like, "The National Urban Diabetes Survey" done by Ramachandran *et al.*[84] revealed that monthly income of an individual was positively related to risk of having diabetes mellitus (p<0.0001). But in our study we could not find such association, probably because most of the study participants are residents of urban slums with fairly uniform economic strata. Overall it shows the Type -2 Diabetes is becoming more prevalent in lower socioeconomic sections of our population, which needs policy measures to cater this population.

Occupation:

In our study, a majority of 32.3% of type 2 diabetics were private employee (consisting of coolie, daily wagers, etc), 32% were government employee (clerks, health workers etc.) and followed by businessman and unemployed who were 23% and 13% respectively. This is comparable to studies done by Manjunath et al.[34], Somappa HK et al.[11] and Jain V et al.[83]

Other Socio – Demographic Variables:

Around 44.9% of the type 2 diabetics in our study belonged to nuclear family, 34.8% to joint family and 20.3% to three generation family. 8.9% of the participants had family history of diabetes mellitus in their first degree relatives.

89.9% of the study participants were married, widow/widower/separated were around 8.9% and unmarried were only 1.3%. This indicates the universality of marriage, in Indian community. 66.5% of our study participants belonged to Hindu religion and remaining 33.5% belonged to Muslim religion.

Risk factors of type 2 diabetics:

Tobacco & Alcohol Consumption:

In our study, among the known type 2 diabetic patients tobacco consumers in both chewing and smoking form were around 26.6% and alcohol consumers were only 9%. Whereas in another study by Jain V et al. at Rural Medical College, Sevagram in 2012 showed 42.8% of the type 2 diabetics were tobacco consumers and 41.4% were alcohol consumers[83]. But, in a study done using WHO - STEPS questionnaire, in Punjab in the year 2014-15 by Tripathy JP et al. revealed that only 7.9% and 10.4% of the known diabetics were current smokers and alcohol consumer's

respectively[85]. This variation in our study could be because of under reporting by the participants or due to life style modification adopted after being diagnosed as type 2 diabetic. Another reason could be presence of 60.1% of female participants in our study.

Dietary habits:

In our study majority of 50.8% of the male participants consumed vegetarian diet, while around 54.7% of female participants consumed mixed diet. This difference in dietary pattern was found statistically significant at 5% level of significance. We also found statistical significance in outside food/snacks consumption patterns among males and females. Here, 18.9% of females consumed outside snacks daily while only 4.8% of males did so. A review article by Waqas Sami *et al.,* stated that, "The role of diet in the etiology of T2DM was first proposed by Indians, who observed that the disease was almost confined to rich people who consumed oil, flour, and sugar in excessive amounts."[86] But this perception is changing as prevalence of diabetes is also increasing in people belonging to lower socio economic status. A Multi Centric study was done by Ambika Satija *et al* to assess the effect of dietary patterns among known diabetics. In this study, dietary patterns was categorized a 'cereals-savoury foods', 'fruit-veg-sweets-snacks' and 'animal-food', which they identified through factor analysis of dietary intake data. They found positive, graded associations across quintiles of the 'animal-food' pattern with both obesity and central obesity, among both men and women, and were consistent in sensitivity analyses[87]. Some studies also suggests that T2DM patients require reinforcement of dietary education, through stakeholders (health-care providers, health facilities, etc.) to encourage them to understand the disease management better, for more appropriate self-care and better quality of life. The overall purpose of treating T2DM is to help the patients from

developing early end-organ complications which can be achieved through proper dietary management[86-88].

Type of work:

The role of physical inactivity in the pathogenesis of type 2 diabetes mellitus (T2DM) has been studied intensively. Lack of physical activity predisposes to T2DM and makes its management more difficult. On the other hand, engaging in regular physical activity can not only prevent the development of T2DM, but can also potentiate the effects of anti-diabetic drug therapy, thereby improving glycaemic control[89]. As per the Physical activity scale used in this study, majority 60.1% of the participants were engaged in moderate level of work. As the study area chosen was an urban slum, sedentary workers were found very minimum, i.e, only 12.7% of males and 7.4% females were sedentary workers. Hence, we could not find any associations with type of work and HbA1c levels.

Family history of DM:

Facts suggest that family history by itself is most useful in predicting disease. When multiple family members are involved, the occurrence of disease may be seen prematurely in subsequent generations of that family[90]. Yang *et al*. further suggested that family history of diabetes could provide significant improvements in detecting undiagnosed cases of diabetes[87]. In an another study, it was found that not only the adults, even the youths with a positive family history showed signs of increased risk for these conditions which indicates the importance of family history approach for screening of at risk children[91]. In our study family history of diabetes was found in 8.9% of the participants. This percentage is comparatively lower in our study than

those done by Das M *et al*. and Valdez R *et al*[91-93] where family history among known diabetics was found in >30%

BMI:

In our study mean BMI of known type 2 diabetics was 27.7 ± 7.1 kg/m^2 and 26.3 ± 6.2kg/m^2 among male and female participant respectively, which is higher compared to Asian Indian Criteria[71]. In a study conducted to assess QOL among known type 2 diabetics in Bulgaria reported the mean BMI as 30.6 ± 5.1kg/m^2 [93]. A study done by Harish Kumar Somappa *et al*. also reported mean BMI among males and females as 26.75 ± 3.85 and 26.23 ± 3.99 respectively which was similar to our study[94]. Majority of 56.3% of our study participants were overweight /obese, according to Asian Indian Classification of BMI[11]. Other studies have also shown, similar results, a study done in Vellore, Tamil Nadu in 2014 by Manjunath K. *et al*. which reported 59% of known type 2 diabetics with overweight or obese[34]. BMI is an independent risk factor for diabetes[94], higher mean BMI in our study demonstrates the strong relation of BMI and type 2 diabetes mellitus.

Abdominal Obesity:

Mean waist circumference in the study population was 78.1 ± 11.5 and 80.7 ± 12.2 among males and females respectively and abdominal obesity was present among 29.7% of the study participants. Study by Somappa HK *et al*. reported no difference in waist circumference among males and females.[11]

Co-morbidities of type 2 DM:

Blood Pressure:

Mean systolic blood pressure of male and female study population was 130±15 mmHg and 131±13 mmHg respectively in our study. In our study, pre hypertensive were 55.1% and hypertension was seen among 27.2% (grade I 24.7% and grade II 2.5%). A review study done by Ann D Colosia *et al*. in the year 2013 revealed the prevalence of hypertension among known type 2 diabetic patients in India as ranging from 22.3 to 42%, which is in agreement with our results[95]. Another study done by Venugopal *et al*. at Vijayanagar Institute of Medical Sciences, Bellary also found the prevalence of hypertension higher among known type 2 diabetics, with prevalence of ≈ 26%[96]. On the other hand, a study by Ashana Shah *et al*. in Manipur found the co − prevalence of hypertension and type 2 diabetes mellitus as ≈ 14%[97]. Hypertension is one of the important co − morbid condition along with type 2 diabetes mellitus in increasing the risk of Cardio Vascular Disease[94].

Depression:

In our study PHQ-9 scale was used to assess depression in known type 2 diabetic. According to PHQ-9, depression is defined as score ≥5; this was present in 19% of our study population. 18.4% of the participants had mild depression (with score 5 − 9) and 0.6% had moderate level of depression (with score 10 - 14). Another study by Amith Thour *et al*. done in 2015 at Chandigarh revealed higher prevalence of depression among type 2 diabetics using same scale; depression with PHQ score ≥5 was 41%, severe depression was reported in 4% of subjects, moderate depression in 10% of subjects, and mild depression in 27% of subjects[98]. Another hospital based study done by Das R *et al*. in West Bengal reported, 46% of major depression and

37% of moderate depression among known type 2 diabetics[99]. This discrepancies in results are due to lack of uniformity in the methodology and smaller sample sizes. Reporting of depression in population based studies is usually low compared to hospital based studies due to sociocultural norms not to express freely .

Blood Sugar Level (HbA1C levels):

HbA1c is a safe indicator of glycemic control in the long-term, and it is considered as the best-glycemic control parameter. Target HbA1c values should be determined according to the risk of each patient's diabetes complications, the presence of other diseases accompanied by diabetes, the life expectancy, and the patient's preferences[100]. In our study, 12% of the participants had poor (>8) HbA1c level and 43% had HbA1c levels in range of 7.1 to 8 among, followed 36.1% having HbA1c levels in the range of 6.5 – 7.0 which is considered good control and it was excellent in only 8.2%. Mean HbA1c among males were 7.4±0.7 and among females 7.1±0.6. This gender difference was statistically significant at p <0.05; and we also found that 20.7% of the male participants had poor (>8.0%) HbA1C levels, while only 6.3% females had so. Hence in our study female participants had better HbA1C levels than male participants. Similar study was done in south Karnataka by Somappa HK *et al*[11], which also used HbA1c levels for eliciting the blood sugar levels of known type 2 diabetics. They did not find any gender difference in HbA1c levels.

In our study levels of BMI from normal to overweight and obese was associated with increasing HbA1c levels in the study participants. Higher BMI independently accounted for poor HbA1c levels in patients with type 2 DM (p=0.013). Another study done at Oman by Jawed AAL *et al.* also showed similar

results but it was not statistically significant[101]. Some previous studies also showed that diabetes and BMI are not independently associated[102].

We assessed, different treatment modalities used by study participants with HbA1c levels. We found that among those participants who used oral hypoglycemic agents (OHA) / insulin users, ≈46% had maintained their HbA1c levels below the target value of <7.5%. It was observed that, there was added effect of dietary advice, advice on physical activity and advice on cessation of alcohol and tobacco consumption among the study participants. We also found that those participants who started using alternate system of medicine for treatment of type 2 DM had higher levels of HbA1c (>7.5%). This was the major highlight of our study as there is increasing trend in usage of such alternate medicine by diabetics in India. Lately, a lot of such products are being made available in the market, with colorful advertisements, thus fooling the vulnerable population. We found that, most common complication was hypoglycemic attack in participants with poor glycemic control but statistical significance was not established, whereas urinary tract infection, neuropathy and retinopathy were highest among these participants with statistical significance at 5% level of significance.

Quality of life in known type 2 diabetics:

Diabetes can have an intense effect on QOL in terms of social and psychological well-being as well as physical health. It is one of the psychologically demanding chronic disease; with social, behavioral & stress factors related to nearly every aspect of the disease and its treatment. Advancement in the treatment modalities of DM has resulted in a longer lifespan[103]. The goal of treatment is no longer limited

to just symptom reduction; but it also involves a holistic approach planned to improve the QOL at large.

In our study, Quality of life among known type 2 diabetic participants was assessed using WHOQOL BREF scale containing 26 questions, containing the four domains viz., physical health domain, psychological domain, social relationship domain and environmental domain.

In our study, using transformed scores of mean values of different domains revealed, highest score for physical health and environmental health domain with 50.5±11.5 and 50.0±8.8 respectively which was followed by psychological and social domain with 47.1±10.8 and 45.8±16.1 respectively. This finding is similar to other studies done by Jain V *et al.,* Patel B *et al.,* Manjunath K *et al*. [11,30,34]. This may be due to major impact of diabetes on sex life[103] and sex life is a major component of social domain and also in population based study like ours, it may not be culturally acceptable to people either report or discuss regarding sexual health in an interview. So, social QOL is affected maximally.

In our study, we have categorized the respondents into poor QOL or good QOL. Individuals with the total mean score of 50% and above were classified as having good QOL and less than 50% as having poor QOL. Using this we found that, in our study population, majority of 56.3% had poor physical QOL and remaining 43.7% had good physical QOL. In psychological domain, majority of 62% had poor psychological QOL and only 38% had good psychological QOL. In social domain, around ≈71% of the study participants had poor social QOL compared to 29% who had good social QOL. It was same in environmental domain also, with 57% having poor environmental QOL and only 43% having good environmental QOL. Another

study done by Manjunath K *et al*.[34] in CMC, Vellore showed different findings from our study. They reported 63% of good and 37% of poor physical QOL; 69% of good and 31% of poor psychological QOL; 27% of good and 73% of poor social QOL and 85% good and 15% poor environmental QOL. Only social domain findings were comparable to our findings.

Physical QOL Domain:

Physical QOL domain deals with the questions related to energy in day to day work, fatigability, pain and discomfort, sleep and rest[30]. Our study population mainly contains participants belonging to poor socioeconomic status and they have reported of higher physical domain score. 82% of the study participants with >60yrs age had poor physical QOL, than the younger participants. This was statistically significant at p<0.05. Another study by Ronak NH *et al*.[104] also showed that poor physical QOL is directly proportional to the age of the participants. In our study, majority of 63.5% of males reported poor physical domain compared to females with only 52% reported poor. On the contrary, study by Manjunath K *et al*.[34] showed that females reported poor physical QOL than male participants.

In our study physical domain was poor among housewives and self employed (among small business man), this can be attributed to the type of work there are involved in and stress; combined with physical constraints due to type 2 diabetes mellitus.

Body mass index was also found to be affecting the physical QOL in our study participants, underweight and normal weight participants reported good physical QOL than overweight and obese study participants. This is comparable with studies done by Ronak NH *et al*.[104], Somappa HK *et al*.[11]

Psychological QOL:

Psychological domain of QOL deals with the aspects like perception of bodily image and appearance, negative feelings, positive feelings, self esteem, thinking, learning, memory and concentration. In our study we found that females had better psychological QOL compared to males, this has been observed by many studies like Patel B *et al*.[30], Jain V et. al.[83] this can be attributed to their openness to feelings[105], when compared to male participants who often don't express or culturally it is not acceptable for males to be expressive about their emotions and they may also be stressed more due to work, occupation and socio economic constraints. Marital status was not attributed to psychological QOL in our study as both married, unmarried and separated/widow /widower had similar psychological QOL. On the contrary, findings from Manjunath K *et al*.[34] and Patel B *et al*.[30] reports better psychological QOL in married compared to single participants. In our study, majority of 75% of the study participants were in Class V SES reported poor psychological QOL, followed by Class IV, II & III respectively. The association of SES with psychological QOL was statistically significant at $p<0.05$. We also found that, $\approx$ 69% of heavy worker, 64.2% of moderate worker had poor psychological QOL scores. 73.3% of sedentary workers had good psychological QOL scores, this was statistically significant at $p<0.05$.

Social Domain of QOL:

Social domain of QOL mainly deals with questions related to personal relationship, social support and sexual activity. Many respondents in our study hesitated in answering the questions related to sex and hence it was not possible to be certain about the reliability of social domain score. This finding demonstrates that the cultural differences affecting social QOL assessment[30]. In our study, we found that,

there was gender difference in social domain as female participants reported better social domain than male participants. Major finding from our study is that study participants who were tobacco consumers (smoking or chewing) and alcohol consumers were having low social domain of QOL. In our study, increase in SES was directly proportional to the increase in percentage of participants in poor Social QOL domain, as majority of 79% of study participants in Class I & II of Modified B. G. Prasad Classification had poor social QOL, and this was followed by Class III, II and I.

Environmental Domain of QOL:

Environmental domain of QOL mainly deals with questions related to financial resources, freedom, physical safety and security, health and social care, accessibility and quality, home environment, opportunities for acquiring new information and skills, participations in and opportunities for recreation/leisure and physical environment (pollution /noise /traffic /climate /transport). In our study we did not find much difference in environmental domain scores, as the study participants were residing in similar neighborhood and hence they were exposed to similar environmental conditions.

Overall QOL and Perceived QOL:

47.6% of the male participants rated their perceived QOL as neither poor nor good, whereas ≈ 38% of female participants rated perceived QOL as poor. Hence, males had better perceived QOL than females; on the contrary females scored better in all QOL domain scores. A study by Manjunath K *et al.*[34] reported better QOL among male participants than female participants, which is similar to our finding. Another study by Somappa HK *et al.*[11] reported that males had lower score for all the

four domains compared to females, this finding is also similar to our study. Eljedi A *et al*[106] also observed that females had lower QOL than males. Similarly Rubin RR observed that men generally report better quality of life than women and younger people report better quality of life than older people[35] Regarding satisfaction with health condition; majority of male participants with ≈ 51% rated it as neither poor nor good, whereas majority of female participants with ≈ 39% rated it as poor. As majority of female diabetics are housewives, it may be difficult for them to cope up with disease, while male patients being occupied reported better overall general health and perceived QOL.

HbA1c levels and QOL:

WHOQOL-BREF domain overall scores were higher in patients with controlled diabetes (i.e., with HbA1c levels either excellent or good) as compared to uncontrolled (i.e., with HbA1c levels either acceptable or poor). There was significant difference in each domain which collectively depicts poorer QOL in uncontrolled diabetics compared to controlled diabetics. This is an important finding of our study.

Factors influencing QOL (Linear regression):

As per the studies conducted previously factors that have been identified as predictors of QOL in known type 2 diabetics are age, female gender, depressive symptoms, tobacco consumption, alcohol consumption, presence of co - morbidities like hypertension, overweight / obesity and abdominal obesity and glycemic level (HbA1c)[30, 107–109]. We applied linear regression to identify the predictors of perceived QOL in our study population. Poor environmental domain scores, mild and moderate depression was found to be predictors of poor perceived QOL in our study population.

Study by Somappa HK *et al.*[11], showed that QOL depends on HbA1c levels by logistic regression, which was not found in our study. Another study by, Manjunath K *et al.*[34] showed that QOL depends on gender, marital status, socio-economic status and BMI of the study participants by regression analysis at $p<0.05$.

SUMMARY

❖ This study was conducted in the urban slums of the field practice area of BLDEU's Shri B M Patil Medical College, Hospital and Research Hospital.

❖ The total number of study participants were 158, among them 63 (39.9%) were male and 95 (69.1%) were female with mean age of 46.7±10.7yrs and 47.8±10.2yrs among them respectively.

❖ Majority of 36.7% of the study participants were in the age group of 30-40 years old.

❖ Majority of ≈ 90% of the study participants were married and around 67% of the study participants belonged to Hindu religion.

❖ Around 37% of the study participants were illiterate or had no formal education, which was closely followed by those who received only primary schooling (35.4%).

❖ Majority of the study participants belonged to Class IV and V of modified B. G. Prasad classification with 35.4% and 30.4% respectively.

❖ Majority of 45% of the study participants belonged to nuclear family, 34.8% to joint family and 20.3% to three generation family.

❖ Major finding our study was, 56.3% of the study participants were overweight and obese (i.e., BMI >25kg/m^2, as per Asian Indian Classification). Around 55.1% of females were overweight /obese, while only 44.9% of males were overweight/obese.

❖ Family history of diabetes was present in 8.9% of participants.

❖ It was also seen in our study that, 24.7% and 2.5% of the known type 2 diabetics were having grade I and II hypertensive disorder respectively; and majority of 55.1% were having pre hypertension.

❖ PHQ-9 item scale used for diagnosis of depression revealed that, among our study participants 18.4% had mild depression, 0.6% had moderate depression.

❖ The HbA1c levels among these known cases of type 2 DM showed that, 12% had maintained blood sugar levels very poorly (>8), 43.7% had maintained are higher level but were acceptable (7.1 − 8), where as 36.1% had maintained at good (6.5 − 7) and excellent (4.5 − 6.4) level. This shows that, around majority of 91.8% of the study participants had HbA1C levels above the target level (i.e., 6.5).

❖ HbA1c levels was found to be more poor in males (20.7%) than females. Also increasing BMI from underweight to normal to overweight or obese was found to associate with worsening of HbA1c levels.

❖ Among the participants with HbA1c levels ≥ 8.0%, we found that 89.4% had UTI, 47.3% had neuropathy, 21% had foot ulcers and 26.3% had retinopathy. This was found statistically significant at 5% level of significance. Hypoglycemia was also found highest with 63.1% but was not of statistical significance.

❖ Among the participants who use Alternate system of medicine for treatment of type 2 DM, we found that ≈73% and ≈21% had their blood glucose level poor at 7.1-8.0 and >8.0% respectively. This finding was statistically significant at 5% level of significance.

❖ The prevalence of abdominal obesity among known type 2 diabetic patients was 29.7%. It was 15.9% in males and 38.9% in females which was statistically significant at p<0.05.

❖ The transformed scores of WHOQOL – BREF scale revealed that, mean score in physical health domain was around 50.5, followed by environmental domain with 50.0, psychological with 47.0 and least in social domain with 45.8.

❖ Individuals with the mean score of 50% and above in each domain of QOL were categorized as having good QOL and those having less than 50% as poor QOL. So, we found that 56.3%, 62%, 70.9% and 57% of the study participants in the QOL domains of physical health, psychological health, social health and environmental health had poor quality respectively.

❖ In our study we found that, as age of the study participants increases, the percentage of poor physical health also increases. In our study, only 58.6% of participants in 30 – 40yrs old age group had poor physical health whereas around 82% of participants >60yrs old had poor physical QOL.

❖ Physical QOL was also found to be associated with BMI of the study participants in our study. Among underweight participants 36.4% had poor physical QOL, whereas in overweight/ obese participants around 52% had poor physical QOL and 67.2% in normal weight participants.

❖ In our study psychological QOL was found to be associated with Socio – Economic Status of the study participants. 75% and 55.4% of study participants belonging to Class V & IV of Modified B. G. Prasad classification respectively had poor psychological QOL, followed by Class III having 48.6% of study participants in poor psychological QOL range.

❖ Majority of around 69% of the participants doing heavy work had poor psychological domain, followed by 64.2% of moderate worker and only 26.7% of sedentary worker.

❖ Social domain of QOL was poor in males compared to females, as 74.6% of males had poor social domain whereas only 68.4% of females had so.

❖ Environmental QOL was found to be better in married participants compared to those either unmarried or widow/widower/separated. As only 54.2% of married people had poor environmental domain and 81.2% of unmarried or widow/widower/separated had so.

❖ The overall perceived QOL was found to be better in male participants than female participants. As only 30.1% of males reported it poor whereas around 38% of females reported so. Similarly satisfaction of health was also found better in males than females, as only 33.3% of males reported it poor compared to females (39%).

❖ This showed that even though females had better QOL in all the domains, there perceived QOL was poor. Similarly, males had poor QOL in all the domains but there perceived QOL was good.

❖ Linear regression of different variables verses perceived QOL showed that, environmental QOL and depression (mental stress) among study participants determines the perceived QOL.

CONCLUSION

The results emphasize occurrence of type 2 diabetes mellitus in younger age group, which highlight the importance of screening of type 2 diabetes mellitus among them. Female gender, alcohol and tobacco consumption, belonging to lower socio – economic status were associated with type 2 diabetes mellitus in our study. These findings have policy implications and show the need for focusing on delivery of Non Communicable Disease health care services among the under privileged.

Overall Men had poor QOL scores compared to women but perceived QOL was better in males compared to females. The results of this study showed that the glycemic control based on the HbA1c values, BMI, abdominal obesity and alcohol and tobacco consumption, depression and complications were associated with the quality of life in people with type 2 diabetes mellitus.

As prevalence of type 2 diabetes is continuously raising in India, special public health initiatives are needed to tackle obesity, behavioral risk factors like alcohol and tobacco consumption coupled with regular glycemic checkups in diabetics. This will have a beneficial effect on control of diabetes and QOL.

RECOMMENDATIONS

1. Community based health education sessions to be given to create awareness about regular blood sugar checkups and screening of co-morbid conditions (hypertension, depression, retinopathy, nephropathy etc.) for known cases of type 2 diabetes mellitus.

2. Primary health care persons should be oriented for early case detection and management of type 2 diabetes under National Programme for Prevention and Control of Cancer, Diabetes, CVD and Stroke (NPCDCS), as it affects the quality of life of person.

3. Special emphasis should be given for life style modification, through health education sessions for target group (obese/overweight, sedentary worker, age >60yr old, etc.).

4. As prevalence of type 2 diabetes is also increasing among tuberculosis patients, bi − directional screening should be done at primary health care levels by joint initiative of NPCDCS and RNTCP (Revised National Tuberculosis Control Programe).

STRENGTHS OF THE STUDY

1. This community based study on QOL in type 2 DM adds data to the scant literature available on this topic in Indian.

2. We used standard scales to measure QOL, depression and risk factor measurement in our study.

3. We used HbA1c Now+ kits to assess the blood glycemic levels as it is a better indicator and this not a commonly measured variable in other community based study on type 2 diabetic patients.

LIMITATIONS OF THE STUDY

1. We could not find the associations in environmental Domain of QOL, as all the study participants resided in similar environmental conditions.

2. Social domain of QOL contained question regarding sexual life, this was poorly answered by study participants because of existing cultural norms.

3. We could not measure hip circumference as it was not culturally accepted by some of the study participants, so waist to hip ratio could not be calculated.

4. Other co – morbid conditions like lipid profile was not carried out due to financial constraints.

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ANNEXURE –I

QUESTIONNAIRE

A. SOCIODEMOGRAPHIC QUESTIONNAIRE

Participant ID

Que code	Questions	Response
A1	Name & Address in detail	
A2	Age in completed years	……………………………….yrs completed
A3	Sex	Male……………1 Female…… …..2
A4	Marital status	Married………1 Unmarried…..2 Widow/widower/separated…..3 Refused ………………………999
A5	Religion	Hindu………………1 Muslim……………..2 Christian…………..3 Others(specify)……………4
A6	Education	No formal schooling……………..1 primary school(<7th std)………2 High school(7th to 10th std)…….3 Pre university(>10th to ≤PUC2)…………4 College/university completed…5 Refused………………………..999
A7	Occupation	Government employee……………1 Private employee…………………..2 Self employed…………………………3 Homemaker……………………………4 Retired…………………………………5 Unemployed…………………………..6 Refused…………………………999
A8	Income	
	a. Total family income per month	Rs.
	b. Total number of family members	
A9	Type of family	Nuclear…………..1 Joint………………..2 Extended…………3 Living alone………4
BEHAVIOURAL DATA		
TOBACCO & ALCOHOL		
A10	Have you ever used tobacco or related products? (Smoking or Smokeless)	No………………..0- **SKIP to A15** Yes………………1

		Refused…….999
A11	How old were you when you first started using tobacco products?	☐ ☐ ☐ yrs completed
A12	Tobacco smoking habit	Current smoker………………1 Ex-smoker……………………2 Refused…………………999
A13	Tobacco chewing habit	Current user………………1 Ex-user……………………2 Refused…………………999
A14	If ex-user, how long did you use tobacco products?	☐ ☐ ☐ Yrs/ months completed
A15	Have you ever consumed an alcoholic drink?	No………………..0- **Skip to A19** Yes………………1 Refused…….999
A16	Alcohol consuming habit	Current user………………1 Ex-user……………………2 Refused…………………999
A17	If you are current user, how often do you consume alcohol?	Daily…………………..1 1 to 3 times a week………2 Once in a week…………..3 Once in 15 days………….4 Once in 1month/occasionally…….5 Refused…………………999
A18	If ex-user, how long did you use alcohol drinks?	☐ ☐ ☐ Yrs/ months completed
DIETARY HABITS		
A19	What is your dietary habit?	Predominantly Vegetarian…………1 Predominantly Nonvegetarian……..2 Mixed………………………………3 Refused…………………999
A20	What type of oil or fat is most often used for meal preparation in your household?	Refined Vegetable oil…………………1 Non-refined vegetable oil………………2 Others(specify)…………………………3 Refused……………………………999
A21	Do you add extra fat to your meal in the form of ghee or oil regularly?	No………………..0 Yes………………1 Refused…….999
A22	On average, how many times in a week do you consume outside food/snacks?	……………………………..number Refused…………………999
A23	On an average how many times in a week do you consume green leafy vegetables?	Daily…………………1 Thrice a week…………2 Twice a week……………3 Once a week………………4 Others(specify)……………………………5 Refused…………………………999
A24	On an average how often do you consume fruits?	Daily…………………1 Thrice a week…………2 Twice a week……………3 Once a week………………4
A25	Do you add extra salt to your food?	No………………..0 Yes………………1

		Refused…….999
TYPE OF WORK		
A26	Does your work involve vigorous-intensity activity that causes large increases in breathing or heart rate like [carrying or lifting heavy loads, digging or construction work] for at least 10 minutes continuously? *If no Skip to A29.*	No………………..0 Yes………………..1 Refused…….999
A27	In a typical week, on how many days do you do vigorous-intensity activities as part of your work?	days
A28	How much time do you spend doing vigorous-intensity activities at work on a typical day?	Hours : minutes └──┴──┘ : └──┴──┘
A29	Does your work involve moderate-intensity activity that causes small increases in breathing or heart rate such as brisk walking [or carrying light loads] for at least 10 minutes continuously? *If no Skip to A32.*	No………………..0 Yes………………..1 Refused…….999
A30	In a typical week, on how many days do you do moderate-intensity activities as part of your work?	days
A31	How much time do you spend doing moderate-intensity activities at work on a typical day?	Hours : minutes └──┴──┘ : └──┴──┘
A32	How much time do you usually spend sitting or reclining on a typical day?	Hours : minutes └──┴──┘ : └──┴──┘
History of diabetes mellitus		
A33	What was your age at the time of diagnosis of diabetes mellitus?	…………………………years.
A34	How were you diagnosed as diabetic for the first time?	1. 2. 3. Refused………………..999
A35	Do you have any family history of DM? If yes, relation (1st degree relative) …………………………………………	No………………..0 Yes………………..1 Refused…….999
A36	Are you currently receiving any of the following treatments/advice for diabetes prescribed by a doctor or other health worker as well as any advice?	Insulin/oral drug…………………1 Advice on diet………….2 Advice to start exercise…………3 Tobacco/Alcohol cessation………4 Herbal/alternate medicine….5
A37	Have you had any complications related to DM in the past 1year already diagnosed by physician.	Hypoglycemia/hyperglycemia…………1 Eye problem(retinopathy)………………2 Renal problem(nephropathy)…………..3 Peripheral tingling or numbness(neuropathy)…………………4 Ulcer & amputation of leg…………..5 Angina/stroke…………………………6

		Hypertension…………………………...7
		UTI……………………………..8
		others……………………………9
		Don't know…………………………888
A38	If yes, have you received treatment for the same on time?	No………………..0 Yes………………1 Don't know…888
A39	Do you have barriers for taking treatment?	No………………..0 Yes………………1 Refused ……..…999
A40	If yes, name 3 important barriers	1……………… 2………………… 3………………… Refused………………999

B. PHQ-9

	Over the LAST 2 WEEKS, how often have you been bothered by…	Not at all	Several days	More than half the days	Nearly every day
B1	little interest or pleasure in doing things?	0	1	2	3
B2	feeling down, depressed or hopeless?	0	1	2	3
B3	trouble falling or staying asleep OR sleeping too much?	0	1	2	3
B4	feeling tired or having little energy?	0	1	2	3
B5	poor appetite OR overeating?	0	1	2	3
B6	feeling bad about yourself – or that you are a failure or have let yourself or your family down?	0	1	2	3
B7	trouble concentrating on things, such as reading a newspaper or watching television?	0	1	2	3
B8	moving or speaking so slowly that other people could have noticed? OR the opposite – being so fidgety or restless that you have been moving around a lot more than usual?	0	1	2	3
B9	thoughts that you would be better off dead or thoughts of hurting yourself in some way?	0	1	2	3

c. WHO-QOL BREF QUESTIONNAIRE

Sl.no.	Questions					
		Very poor	**Poor**	**Neither poor nor good**	**Good**	**Very good**
C1	How would you rate your quality of life?	1	2	3	4	5
		Very dissatisfied	**Dissatisfied**	**Neither satisfied nor dissatisfied**	**Satisfied**	**Very satisfied**
C2	How satisfied are you with your health?	1	2	3	4	5
		Not at all	**A little**	**A moderate amount**	**Very much**	**A extreme amount**
C3	To what extent do you feel that physical pain prevents you from doing what you need to do?	5	4	3	2	1
C4	How much do you need any medical treatment to function in your daily life?	5	4	3	2	1
C5	How much do you enjoy life?	1	2	3	4	5
C6	To what extent do you feel your life to be meaningful?	1	2	3	4	5
C7	How well are you able to concentrate?	1	2	3	4	5
C8	How safe do you feel in your daily life?	1	2	3	4	5
C9	How healthy is your physical environment?	1	2	3	4	5
		Not at all	**A little**	**Moderately**	**Mostly**	**Completely**
C10	Do you have enough energy for everyday	1	2	3	4	5

	life?					
C11	Are you able to accept your bodily appearance?	1	2	3	4	5
C12	Have you enough money to meet your needs?	1	2	3	4	5
C13	How available to you is the information that you need in your day to day life?	1	2	3	4	5
C14	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5
		Very poor	**Poor**	**Neither poor nor good**	**Good**	**Very good**
C15	How well are you able to get around?	1	2	3	4	5
		Very dissatisfied	**Dissatisfied**	**Neither satisfied nor dissatisfied**	**Satisfied**	**Very satisfied**
C16	How satisfied are you with your sleep?	1	2	3	4	5
C17	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
C18	How satisfied are you with your capacity for work?	1	2	3	4	5
C19	How satisfied are you with yourself?	1	2	3	4	5
C20	How satisfied are you with your personal relationships?	1	2	3	4	5
C21	How satisfied are you with your sex life?	1	2	3	4	5

C22	How satisfied are you with the support you get from your friends?	1	2	3	4	5
C23	How satisfied are you with the conditions of your living place?	1	2	3	4	5
C24	How satisfied are you with your access to health services?	1	2	3	4	5
C25	How satisfied are you with your transport?	1	2	3	4	5
		Never	**Seldom**	**Quite often**	**Very often**	**Always**
C26	How often do you have negative feelings such as blue mood, despair, anxiety & depression?	5	4	3	2	1

d. MEASUREMENTS

D1	Height	In Centimeter (cm)
D2	Weight	In kilogram (kg)
D3	Body Mass Index (BMI)	In kg/m^2
D4	Blood pressure (SBP)	Systolic (mm Hg) ……………………………………………
D5	Blood pressure (DBP)	Diastolic (mm Hg) ……………………………………………
D6	HbA1c level	
D7	Waist circumference	in cm………………………

ANNEXURE –II

ETHICAL CLEARANCE CERTIFICATE

B.L.D.E.UNIVERSITY'S
SHRI.B.M.PATIL MEDICAL COLLEGE, BIJAPUR – 586103
INSTITUTIONAL ETHICAL COMMITTEE

NO/58/2015
20/11/15

INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The Ethical Committee of this college met on ___17-11-2015___ at ___03 pm___ 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 accorded Ethical Clearance.

Title "A study to assess the quality of life (QOL) in kno -wn type 2 diabetes mellitus patients aged 30-65 years resi -sting in urban field practice area of Shri, B M patil medical college Hospital & Research centre"

Name of P.G. Student : ___Dr. Tanuja Pattankar.___
___Dept of Community Medicine___

Name of Guide/Co-investigator : ___Dr. Shailaja. S. Patil___
___professor___

DR.TEJASWINI VALLABHA
CHAIRMAN
CHAIRMAN
Institutional Ethical Committee
BLDEU's Shri B.M. Patil
Medical College, BIJAPUR-586103.

Following documents were placed before E.C. for Scrutinization
1) Copy of Synopsis/Research Project
2) Copy of informed consent form.
3) Any other relevant documents.

112

INFORMED CONSENT FORM

B. L. D. E UniversityShri B.M. Patil Medical College, Hospital And Research Centre, Vijayapura
Department Of Community Medicine

CONSENT FORM

TITLE OF TOPIC: A STUDY TO ASSESS THE QUALITY OF LIFE (QOL) IN KNOWN TYPE 2 DIABETES MELLITUS PATIENTS AGED 30 -65 YEARS, RESIDING IN URBAN FIELD PRACTICE AREA OF SHRI B M PATIL MEDICAL COLLEGE, HOSPITAL & RESEARCH CENTRE.

GUIDE : Dr.SHAILAJA S.PATIL

PG STUDENT : Dr.TANUJA PATTANKAR

PURPOSE OF RESEARCH:

I have been informed that this study will help to assess the Socio demographic, and quality of life in known cases of type 2 DM cases. The study is intended to interview the adults aged more than 18 yrs residing in Urban Slum of field practice area of Community Medicine Department of Shri B M Patil Medical College, Hospital and Research Centre, Vijayapur.

PROCEDURE:

I understand that this is a Community based programme. In this procedure I will be asked a series of questions by the researcher regarding the topic.

RISK AND DISCOMFORTS:

I understand that I may experience some discomfort during this procedure. This is mainly result of conditions. 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 assess Socio demographic, Cultural and Negative life events in cases of depression of age group 18-60yrs.

CONFIDENTIALITY:

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

REQUEST FOR MORE INFORMATION:

I understand that I may ask more questions about the study at any time to Dr.Tanuja Pattankar 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.Tanuja Pattankar may terminate my participation in the study at any time after she has explained the reasons for doing so.
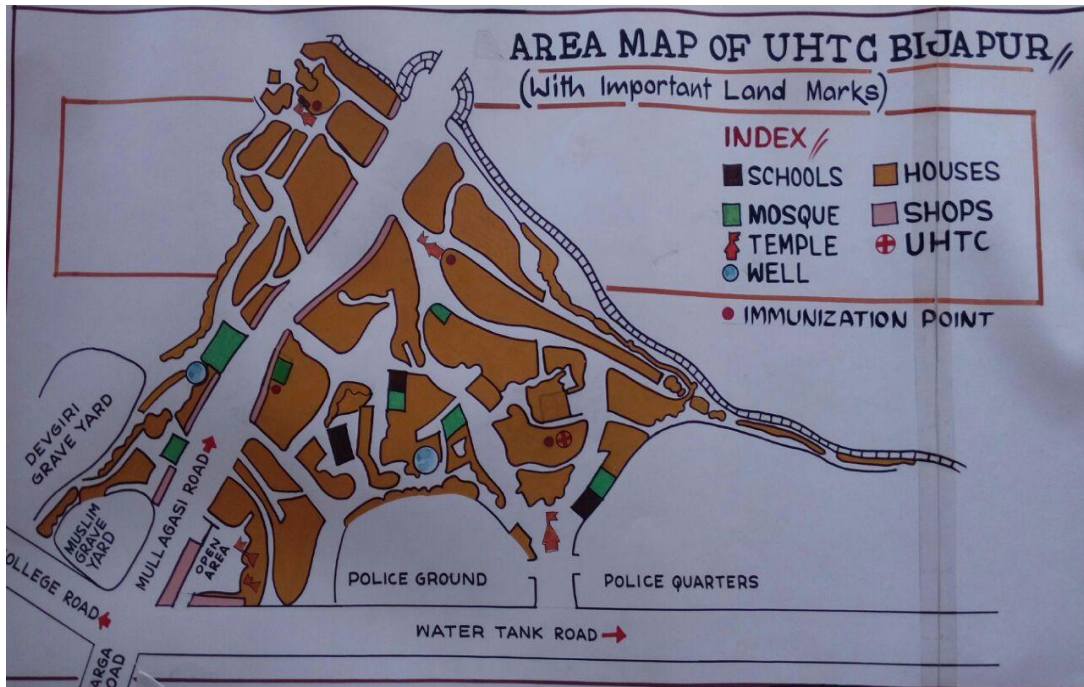
(Guide / Principle Investigator)   (Date)

(Investigator)   (Date)

ANNEXURE –IV

MAP OF URBAN FIELD PRACTICE AREA

ANNEXURE V: Gantt chart

Activity	2015							2016												2017									
	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct
Topic selection	■	■																											
Synopsis preparation and submission			■	■	■																								
Review of literature					■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■		
Preparation of Proforma				■	■																								
HbA1c Kits ordered							■	■																					
Analysis and instrument modification								■	■																				
Data collection									■	■	■	■	■	■	■	■	■	■											
Data analysis																				■	■	■	■	■	■				
Dissertation writing																								■	■	■	■	■	
Dissertation submission																													■

ANNEXURE –V

PHOTOGRAPHS