Compliance to treatment among Type II diabetics receiving care at peripheral mobile clinics in Kaniyambadi block of Vellore district.

By

Dr. Divya Muliyil

CERTIFICATE

This is to certify that the dissertation titled "**COMPLIANCE TO TREATMENT AMONG TYPE II DIABETICS RECEIVING CARE AT PERIPHERAL MOBILE CLINICS IN KANIYAMBADI BLOCK OF VELLORE DISTRICT"** is abonafide work of Dr. Divya Muliyil in partial fulfillment of the requirements for the MD Community Medicine (final) examination (Branch XV) of the TN Dr. MGR Medical Universityto be conducted in April 2013.

Signatures:

Guide	**Head of the Department**	**Principal**
Dr. VenkataRaghava Mohan	Dr. Kuryan George	Dr. Alfred Daniel
Associate Professor	Professor	Professor & Head
Dept. of Community Health	Dept. of Community Health	Dept. of Orthopaedics
Christian Medical College,	Christian Medical College,	Christian Medical College,
Vellore 632002	Vellore 632002	Vellore 632002

ACKNOWLEDGEMENTS

I am very grateful to a lot of people who have helped me with this dissertation. Firstly I would like to acknowledge the contribution of all the participants without which this would not have been possible.

Mrs.Gifta and the Public health nurses who translated the questionnaire into Tamil.

The Health Aides, Part time community Health workers Mr.Venkatesan and countless other people in the village who helped me find my way around and made data collection possible.

Mrs.Vanitha from Biochemistry who helped process all the blood samples.

Mrs.Shanthi, a software programmer in CHAD, for helping with data analysis

My teachers Dr. JayaprakashMuliyil, Dr. Kuryan George, Dr. Reginald Alex and Dr. Jasmine for all their support and guidance through the entire process.

My family for their constant support and encouragement

And last but not the least I specially thank my guide Dr.VenkataRaghava for his continuous support through every step of the way.

..

ABSTRACT

TITLE OF THE ABSTRACT : COMPLIANCE TO TREATMENT AMONG TYPE II DIABETICS RECEIVING CARE AT PERIPHERAL MOBILE CLINICS IN KANIYAMBADI BLOCK OF VELLORE DISTRICT.

DEPARTMENT : COMMUNITYMEDICINE

NAME OF THE CANDIDATE : DR. DIVYA ELIZABETH MULIYIL

DEGREE AND SUBJECT : M.D. COMMUNITY MEDICINE

NAME OF THE GUIDE : DR. VENKATARAGHAVA

OBJECTIVES:

To measure:

1.   The rate of compliance to oral hypoglycemic agents,

2.   The level of physical activity and caloric intake and

3.   The level of glycemic control among diabetics managed in the periphery.

4.   To measure the association between each of these factors independently and in combination with glycemic controls.

METHODS:

A cross sectional study was done. One hundred participants were randomly selected for the study. All those above the age of thirty, being treated for diabetes mellitus type 2 in the doctor-run mobile clinic were eligible to participate in the study. Those on insulin therapy and those bedridden were not included. The following parameters were measured for each person:

(a)   Diet intake

(b)   Physical activity

(c)   Compliance to therapy

(d)   Glycated hemoglobin

Correlation between these factors and glycemic control was measured.

RESULTS:

Out of the 100 participants, 74% were female, and47% were from the upper middle class. Those who were taking 80% of the expected number of pills were classified as compliant and it was found that 50.5% of those prescribed metformin were compliant and 45.3% of those prescribed glibenclamide were compliant.

The mean caloric intake per day was 1614.83 Kcals (95%CI 1494.6- 1735.1)

Out of the 100 participants 39% had a sedentary lifestyle and 60% had moderately active lifestyle.

The mean Hba1c was 7.3% and 48.8% had ideal glycemic control. The remaining 25.6% had unsatisfactory control.

No correlation was found between sedentary lifestyle and uncontrolled sugars. It was found that HbA1c significantly reduced with better adherence.

TABLE OF CONTENTS

Office of the Addl. Vice Principal (Research)   Christian Medical College,
                                                 Vellore 632 002

Ref: Res/02/2012   March 8, 2012

Dr. Divya Muliyil
PG Registrar
Department of Community Health
Christian Medical College
Vellore 632 002

Dear Dr. Muliyil,

Sub: **FLUID Research grant project NEW PROPOSAL:**
          Compliance to treatment of diabetes among patients with diabetes mellitus type 2
          being managed at the community level.
          Dr. Divya Muliyil, PG Registrar, Community Health, Dr. Venkataraghava, Dr.
          Reginald Alex, Community Health.

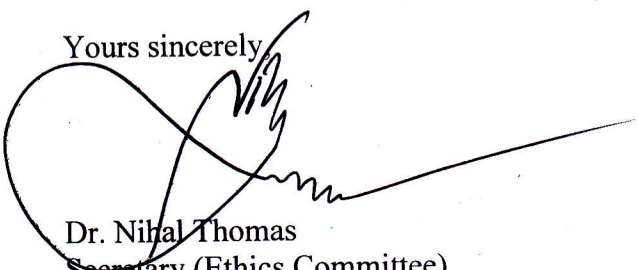Ref: IRB Min. No. 7753 dated 6.2.2012

I enclose the following documents:-

1.   Institutional Review Board approval
2.   Agreement

Could you please sign the agreement and send it to Dr. Nihal Thomas, Addl. Vice
Principal (Research), so that the grant money can be released.

With best wishes,

Yours sincerely,

Dr. Nihal Thomas
Secretary (Ethics Committee)
Institutional Review Board

INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE
VELLORE 632 002, INDIA

Dr.B.J.Prashantham, M.A.,M.A.,Dr.Min(Clinical)
Director, Christian Counseling Centre
Editor, Indian Journal of Psychological Counseling
Chairperson, Ethics Committee, IRB

Dr. Alfred Job Daniel, MS Ortho
Chairperson, Research Committee &
Principal

Dr. Nihal Thomas
MD, MNAMS, DNB(Endo), FRACP(Endo), FRCP(Edin)
Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

March 8, 2012

Dr. Divya Muliyil
PG Registrar
Department of Community Health
Christian Medical College
Vellore 632 002

Sub: **FLUID Research grant project NEW PROPOSAL**:
Compliance to treatment of diabetes among patients with diabetes mellitus type 2
being managed at the community level.
Dr. Divya Muliyil, PG Registrar, Community Health, Dr. Venkataraghava, Dr.
Reginald Alex, Community Health.

Ref: IRB Min. No. 7753 dated 6.2.2012

Dear Dr. Muliyil,

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project entitled "Compliance to treatment of diabetes among patients with diabetes mellitus type 2 being managed at the community level" on February 6, 2012.

The Committees reviewed the following documents:

1.   Format for application to IRB submission
2.   Informed Consent Form (English and Tamil)
3.   Questionnaire (English and Tamil)
4.   WHO STEPS questionnaire
5.   Cvs of Drs. Venkata Raghava, Reginald Alex
6.   A CD containing documents 1 – 5

The following Institutional Review Board (Ethics Committee) members were present at the meeting held on February 6, 2012 in the CREST/SACN Conference Room, Christian Medical College, Bagayam, Vellore- 632002.

INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE
VELLORE 632 002, INDIA

Dr.B.J.Prashantham, M.A.,M.A.,Dr.Min(Clinical)
Director, Christian Counseling Centre
Editor, Indian Journal of Psychological Counseling
Chairperson, Ethics Committee, IRB

Dr. Alfred Job Daniel, MS Ortho
Chairperson, Research Committee &
Principal

Dr. Nihal Thomas
MD, MNAMS, DNB(Endo), FRACP(Endo), FRCP(Edin)
Secretary, Ethics Committee, IRB
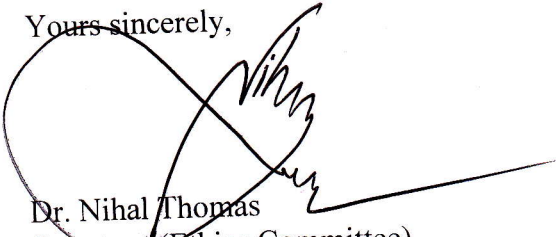Additional Vice Principal (Research)

Name	Qualification	Designation	Other Affiliations
Dr. B.J.Prashantham	MA (Counseling), MA (Theology), Dr Min(Clinical)	Chairperson(IRB)& Director, Christian Counselling Centre	Non-CMC
Mr. Harikrishnan	BL	Lawyer	Non-CMC
Mrs. S. Pattabiraman	BSc, DSSA	Social Worker, Vellore	Non-CMC
Mrs. Ellen Ebenezer Benjamin (on behalf of Dr. Jayarani Premkumar)	M.Sc. (Nursing), Ph.D.	Nursing Superintendent, CMC.	
Mrs. Shirley David (on behalf of Dr. Jayarani Premkumar)	M.Sc. (Nursing), Ph.D.	Nursing Superintendent, CMC.	
Dr. Nihal Thomas	MD MNAMS DNB(Endo)FRAC FRCP(Edin)	Secretary IRB (EC)& Dy. Chairperson (IRB), Professor of Endocrinology & Addl. Vice Principal (Research), CMC.	

We approve the project to be conducted as presented.

The Institutional Ethics Committee expects to be informed about the progress of the project, any serious adverse events occurring in the course of the project, any changes in the protocol and the patient information/informed consent and requires a copy of the final report.

A sum of ₹ 36,500/- (Rupees thirty six thousand five hundred only) can be sanctioned for 12 months.

Yours sincerely,

Dr. Nihal Thomas
Secretary (Ethics Committee)
Institutional Review Board

TEL : 0416 - 2284294, 2284202   FAX : 0416 - 2262788, 2284481   E-mail : research@cmcvellore.ac.in

1. INTRODUCTION AND JUSTIFICATION

Diabetes mellitus has been recognized for long and in all ancient civilizations (1). The endeavour to understand and treat this condition is a long one. Numerous studies have been conducted to understand its etiopathogenesis, progression and treatment (1). The incidence of diabetes is increasing and the onset is at a younger age. Diabetes related complications are on the rise, thereby creating a large burden on the health care system (2).

With the current knowledge and understanding of the disease, prevention is not possible but early diagnosis and treatment is possible (3). If this is neglected we may have a large portion of our population suffering from complications associated with diabetes such as coronary heart disease, peripheral vascular disease and diabetic retinopathy which can result in severe debilitation.

Treatment of this condition however has other challenges. The treatment of diabetes is lifelong and it involves the use of medication every day, changes in lifestyle in terms of diet, exercise patterns and with at least the one check up every quarter(4). These requirements will drastically change a persons' life. All these pharmacological and non-pharmacological methods target one end point – good glycemic control. Adequate glycemic control greatly depends on the patient's adherence to the treatment.

Many strategies have been studied to improve adherence. One such strategy is to educate the patient and make him/her an expert on diabetes (5). Teaching patients to use home blood glucose monitors and to adjust doses of insulin and oral hypoglycemic agents empowers them to control their sugars. Interventions such as 'education about diabetes, home visits, motivational interviewing' and 'problem solving treatment' administered by public health nurses have been studied through randomized clinical trials (4).

There are three possible approaches to control the problem of diabetes – firstly a community based intervention, secondly a clinic based intervention to target high risk patients and thirdly a combination of the two methods (6).

The Community Health and Development (CHAD) programme initiated by the Community Health Department of the Christian Medical College, Vellore, India, has been providing integrated health and development services to the people of Kaniyambadi block with a population of around 108,000 in North Arcot district since 1975. The primary care component of the program involves a health care team consisting of health aides, public health nurses and doctors. Through a mobile clinic which visits every village once a month this team identifies people who need treatment for various medical problems including diabetes mellitus. This team, through their mobile clinic, conducts monthly health check-ups for all those diagnosed to have diabetes mellitus and prescribes the needed drugs at a subsidized rate depending on the affordability of the patients. The Department of Community Health also conducts regular health education programs in every village and through street theatre and educates the community about the

symptoms of diabetes, the need for regular treatment, lifestyle changes required and complications of diabetes.

Thus the CHAD programme aims at improving the glycemic control among diabetics by improving their knowledge about diabetes and by providing regular health care. This study aims to assess the glycemic control of diabetics who managed at the periphery and measure their compliance to treatment. The findings from this study will provide a better insight into the performance of the diabetes management component of the CHAD programme and would provide valuable inputs towards improving the existing diabetes management component thereby improving the quality of lives of diabetics who utilize the CHAD program as their primary source of health care in Kaniyambadi block.

2. AIMS AND OBJECTIVES

Aim:

To estimate the rate of compliance to the treatment of diabetes mellitus among individuals in the Kaniyambadi block, Vellore district in rural South India.

Objectives

To measure the rate of compliance to oral hypoglycemic agents among patients with diabetesmellitus type 2, being treated at the monthly doctor run mobile clinics by the Department of Community Health, Christian Medical College in Kaniyambadi block of Vellore district.

1.   To measure the level of compliance, physical activity and caloric intake among these patients.

2.   To assess the level of glycemic control among diabetics managed at the periphery.

3.   To measure the association between physical activity, diet and compliance with drugs independently and in combination with glycemic control.

Hypothesis

People with diabetes can achieve adequate glycemic control by being treated at the periphery through doctor –run mobile clinics.

3. LITERATURE REVIEW

3.1 Diabetes Mellitus- An overview

3.1.1 Definition:

"The term diabetes mellitus describes a metabolic disorder of multiple etiologies characterized by chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both" (7).

3.1.2 History of diabetes:

The earliest references to the disease mentioning the symptoms of polyuria and complications such as gangrene can be found in the ancient papyruses from the Egyptian civilization dating back to 1552 BC.   In 1500 BC Indian thinkers noticed that ants were attracted to the urine of people who had a certain condition.   The father of Indian medicine, Susruta, in his Samhita has described this condition as "madhumeha"(meaning excreting urine which has a taste of honey)(8). Traditional healers of every ancient civilization have described this condition. It was noted in very early years that there were two forms of this illness- one that affected children and one that was associated with

sedentary life. It was also noticed that children affected by this condition had a very poor prognosis, living only for around 6 months (8).

Aretaeus of Cappadocia, a Greek physician, in the first century BC, coined the term 'diabetes'. The term originated from the Greek word *diabainein* which means 'to siphon' (1). He also described the main symptoms of frequent urination, excessive thirst and increased appetite. He was not able to treat this disease successfully and summarized the life of a diabetic in these words- "short, disgusting and painful".

Over the centuries many modes of treatment have been tried with varying rates of success. The treatment of diabetes with insulin started in 1922 with the discovery of insulin and its role in the metabolism of blood glucose, thanks to the work done by Banting and Best (9). Over the years thereafter other pharmacological therapies were developed. Sulphonylureas were introduced in the 1940's and biguanides were re-introduced in the 1950's.

3.1.3 Glucose metabolism in a non- diabetic person:

After a meal the plasma sugar levels rise and prevents the release of NEFA (Non esterified Fatty acids) from the adipose tissue. This results in a fall in the fatty acid oxidation and stimulation of insulin production. Insulin promotes the uptake of insulin into various tissues in the body. As glucose uptake occurs hepatic production of glucose is inhibited. Hepatic production of glucose in an ongoing process as the brain requires a constant supply of glucose (10).

Figure 3.1: Glucose metabolism in the human body
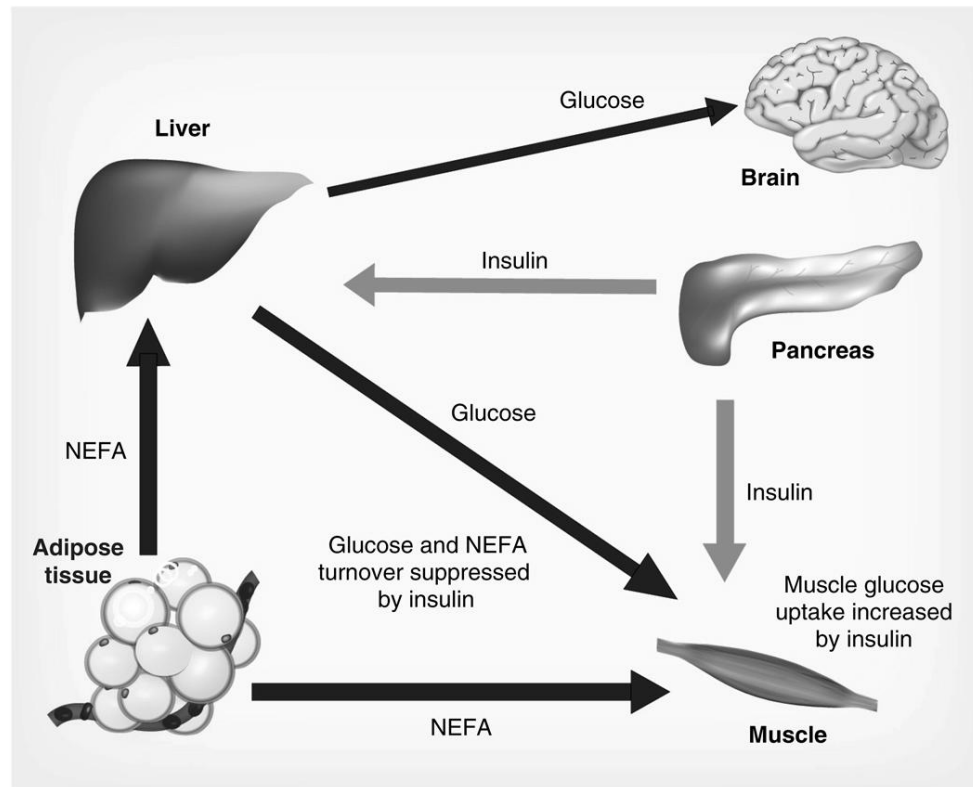
Source: spectrum.diabetesjournal.com

3.1.4 Pathogenesis:

Type 2 diabetes, which is also called adult onset diabetes or non-insulin dependent diabetes, is the result of a combination of many factors. This disease condition has a gradual onset and remains undiagnosed for the initial part of the disease process. Some of the important factors which have found to increase the risk of developing diabetes are: family history of diabetes, past history of gestational diabetes, obesity, hypertension, dyslipidemia and ethnicity.

3.1.5 Diagnosis of Diabetes mellitus type 2:

The classical symptoms of diabetes mellitus include polyuria, polyphagia and polydipsia. People with symptom suggestive of diabetes are advised to test their blood sugars and any one value exceeding the limits for blood sugars according the WHO classification is diagnosed to have diabetes.

Table 3.1: WHO diagnostic criteria (values for the diagnosis of diabetes mellitus and other categories of hyperglycemia:

	Fasting venous blood (plasma)	2 hour post prandial venous blood(plasma)
Diabetes mellitus	>=126mg/dl	>=200mg/dl
Impaired fasting glycemia	111-125mg/dl	<140mg/dl
Impaired glucose tolerance	<126mg/dl	140-200mg/dl

3.1.5 <u>Classification of Diabetes Mellitus</u>:

Diabetes mellitus is classified based on its etiology. The revised WHO Classification of Diabetes Mellitus was published in 1999 as follows (7):

(1)   TYPE 1:

-       Autoimmune
-       Idiopathic

(2)   TYPE 2

-       Insulin resistance with relative insulin deficiency or
-       Secretory defect with or without insulin resistance

(3)   OTHERS

(a)   Due to specific mutations resulting in increased genetic susceptibility

-       Genetic defects of beta cell function (Eg: Maturity Onset Diabetes of the Young)
-       Genetic defects in insulin action

(b)   Diabetes associated with other diseases and pathological conditions

-       Diseases of the exocrine pancreas

   - Fibrocalculouspancreatopathy
   - Pancreatitis
   - Trauma/ neoplasia

-       Endocrinopathies

   - Cushing's
   - Acromegaly

-       Drug induced
-       Infections

   - Congenital rubella
   - Cytomeglovirus

-       Other genetic syndromes

The current classification of diabetes is based on the etiology and is as follows (11):

Figure 3.2: The current classification of Diabetes Mellitus
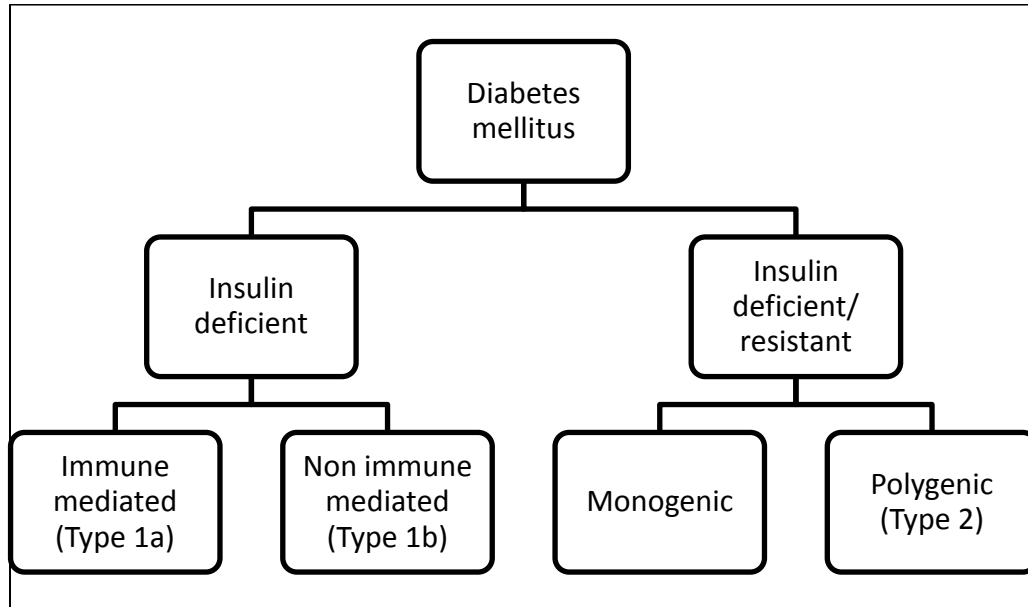
Insulin deficient diabetes:

Types 1a and 1b account for 5-20% of all diabetics. Type 1b is also called Fulminant/ African type of Diabetes.

Type 1 diabetes mellitus: is characterized by beta cell destruction caused by an autoimmune process usually leading to absolute insulin deficiency (12).

Type 2 diabetes mellitus: is the most common form of diabetes mellitus and many factors contribute to the development of this condition. It is characterized by a combination of inadequate insulin secretion and action (12).

3.1.6 Treatment of diabetes:

The Indian Council for Medical Research (ICMR) has laid down targets for the treatment of Diabetes mellitus. These targets are just guidelines. Ideally targets of therapy must be individualized.

Tight control of sugars is recommended in individuals with end organ damage and control of sugars may be "relaxed" in elderly (13).

Table 3.2: ICMR Guidelines for Management of Type 2 Diabetes- 2005

	Ideal	Satisfactory	Unsatisfactory
Fasting plasma sugars	80-110	111-125	>125
2 hour post prandial s	120-140	140-180	>180
HbA1c	<7 %	7-8%	>8%

Diet in Type 2 Diabetes:

It was in the year 1675 that Thomas Willis measured the sweetness of the urine and proposed that it originated from the blood. He was the first to advise a diet high in carbohydrates but low in calories.

Currently, diet restrictions are routinely advised to all individuals with diabetes mellitus and universally accepted as the first line of treatment. The diet usually advised to a

diabetic is a low caloric diet in which the carbohydrate content is 50%, the fats are restricted to <30% and one which has a high amount of dietary fibre.

Many studies have been done to study the benefits of this diet composition. One such study was done in Austria, on 35 obese diabetics, to determine the optimal diet to control sugars and lipids in patients with diabetes. They were all advised a diet of 1600 kilocalories with different diet compositions. The study found that this moderate energy restriction resulted in weight loss and the decrease of blood sugars irrespective of the diet composition (14).A Cochrane systematic review of RCTs involving different diet intervention of more than 12 weeks duration was done and this showed no significant changes in weight or glycemic control on the long run. Also, none of the diets studied (low carbohydrate diet, low fat diet, usual care diet and low glycemic index diet) showed any extra benefits (15).

Patients with diabetes are commonly advised a diet with high carbohydrate content and this is a matter of debate. On many occasions it has been proven that a high carbohydrate diet causes an increase in plasma insulin and triglycerides resulting in a rise of blood sugars in the post prandial period (16). Studies have also shown that when dietary fibre is combined with the high carbohydrate diet blood sugars are better controlled (7). The mechanism is not fully understood but it has been proposed that dietary fibre retards digestion and absorption (16). Based on this it has been proposed that all food with high fibre content will have low glycemic index and will help in glycemic control.

An interventional study done in Japan looking at the benefits of diet in glycemic control and prevention of nephropathy revealed that a moderate to low carbohydrate diet (38%

carbohydrate) resulted in a significant reduction in body mass index, HbA1c,and in the excretion of urinary albumin (17).

A Cochrane systematic review of 36 randomized controlled trials studying low fat/high carbohydrate diets, high fat/low carbohydrate diets, low calorie (<1000 kilocalories per day) diets and very low calorie diets (<500 kilocalories per day) revealed there was not enough evidence to support dietary restrictions in the management of diabetes mellitus type 2 (18). However it did show that regular exercise was found to be useful in achieving good glycemic control.

Exercise in Type 2 Diabetes:

Exercise has been found useful in the control of diabetes. High levels of free fatty acids in the plasma result in inhibition of the enzymes pyruvate dehydrogenase and phosphofructokinase and this results in reduction in the uptake of glucose. Exercise has been shown to be useful by decreasing the amount of circulating free fatty acids and thus improving glucose uptake. Exercise has also been shown to improve insulin sensitivity of tissues (19).

Studies done in south India have revealed that "sedentarism" - the adoption of sedentary behavior is on the rise, and this is contributing to the growing diabetic epidemic in the country (20).Weight reduction in obese patients has been found to be a useful in achieving good glycemic control (21).

A Cochrane systematic review of 8 clinical trials involving 2241 participants randomized to exercise and diet and another 2509 to standard recommendations for individuals without diabetes revealed the following results. The risk of developing diabetes among the

individuals on exercise and diet was reduced by 37% when compared to the individuals who were neither on diet nor exercise. An improvement was seen in body weight, waist circumference and blood pressure. However no benefits were seen in terms of reduction of cardiovascular morbidity, all cause morbidity and quality of life. This systematic review concluded that diet and exercise in combination helped in reducing the risk of developing diabetes but the role of exercise alone in the prevention of diabetes needs further research (3).

Oral Hypoglycemic Agents (OHAs):

Many individuals diagnosed to have type 2 Diabetes will be unable to achieve adequate glycemic control with lifestyle modifications alone and will require oral hypoglycemic agents. Oral hypoglycemic agents are classified based on their mechanism of action (22).

The commonly used oral hypoglycemic agents fall into 4groups:

1.   Sulphonylureas, which are secretagogues: (Example: glibenclamide, glipizide, glimepiride and Gliclazide)

2.   Biguanides (Example: Metformin), which reduce hepatic glucose production

3.   Thiazolidinediones(Example: Pioglitazone and Rosiglitazone), which have an insulin sensitizing action.

4.   Alpha glucosidase inhibitors (Example: Acarbose) which delays the digestion and absorption of carbohydrates from the intestine.

OHAs are initiated at low doses and the titrated upwards based on the glycemic control achieved (22).

Each drug has its own profile of adverse effects. Decisions about long term therapy with OHAs should be taken after considering the tolerability and convenience. The first 3 classes of oral hypoglycemic agents have been found to cause a 1-2% decrease in the HbA1c. Alpha glucosidase inhibitors have not been found to be as effective.

Metformin:

Many studies have been done to explore the benefits of metformin and to see if they go beyond good glycemic control. A systematic review of 29 trials including studies measuring outcomes such as mortality, morbidity, quality of life and glycemic control was done. These studies compared metformin versus sulphonylureas, placebos, diet, thiazolidinediones and insulin. It was found that a significant reduction in the risk of mortality and diabetic complications was found in obese patients on metformin when compared to those on placebo and diet. A moderate benefit was seen in terms of glycemic control, reduction of LDL and reduction of weight and BMI when compared to those on sulphonylureas(23). Some of the common side effects caused by metformin are gastrointestinal side effects such as gastritis and diarrhoea. Metformin Extended release (Metformin XR) is a preparation that requires less frequent dosing and is associated with fewer gastrointestinal side effects and better compliance (24).

Sulphonylureas:

Hypoglycemia is a side effect that is commonly seen among those being treated for diabetes mellitus. The greatest risk for hypoglycemia is among those using insulin

followed by those using sulphonylureas. Studies have shown that a hypoglycemic event was associated with s significant risk ofnon-compliance in the form of discontinuation of drug therapy. Patients with hypoglycemia also have been found to have a significantly higher expenditure on diabetes related health care (25).

Thiazolidinediones:

This is a group of oral hypoglycemic agents. Trials have shown that this group of OHA's is as effective as the others. However it has not been found to have any benefits in terms of preventing cardiovascular or peripheral vascular morbidity. Compared to other OHA's it was found to cause more pedal edema (26).

3.1.7 Maintaining good glycemic control in diabetes:

Role of Hemoglobin A1c in measuring Glycemic control:

Hemoglobin A1c (HbA1c) was first discovered in 1958 and was described as a characteristic of diabetes in 1969.Also known as glycosylated hemoglobin, glycohemoglobin, hemoglobin A1c or hemoglobin A1, measurement of the HbA1c levels gives an average of the plasma sugars over the last 3 months. The advantage of this method is that the specimen can be collected at any time of the day irrespective when the patient has had his last meal (27).

Table 3.3: Average blood sugars in mg/dl that corresponds to HbA1c values:

HbA1c	Average blood sugars in mg/dl
4	60
5	90
6	120
7	150
8	180
9	210
10	240
11	270
12	300
13	330
14	360

HbA1c may be measured using the following analytical methods:

- HPLC (high performance liquid chromatography)

- Affinity chromatography,

- Electrophoresis,

- Immunoenzymatic and

- Immunoturbidometric methods

The UK Prospective Diabetes Study concluded that lower blood sugars reduced the risk of microvascular complications. This was measured using a Bio-Rad Diamat analyser and the reference value used was 4.5-6.2% (28).

Impact of good glycemic control:

A longitudinal cohort study conducted by the Diabetes Control and Complications Trial Research Group, followed 1441 patients with IDDM for a period of 6.5 years has revealed that tight control of sugars decreased the risk of developing retinopathy, micro albuminuria and the risk of developing clinical neuropathy thus preventing macro vascular and micro vascular complications and also resultedin a higher risk of hypoglycemia (29). Though this study was done on people with insulin dependent diabetes the authors have extrapolated these results to those with non-insulin dependent diabetes mellitus.

3.1.8 Complications of Diabetes Mellitus:

The complications of diabetes can be classified as follows:

Figure 3.3: Complications of Diabetes Mellitus
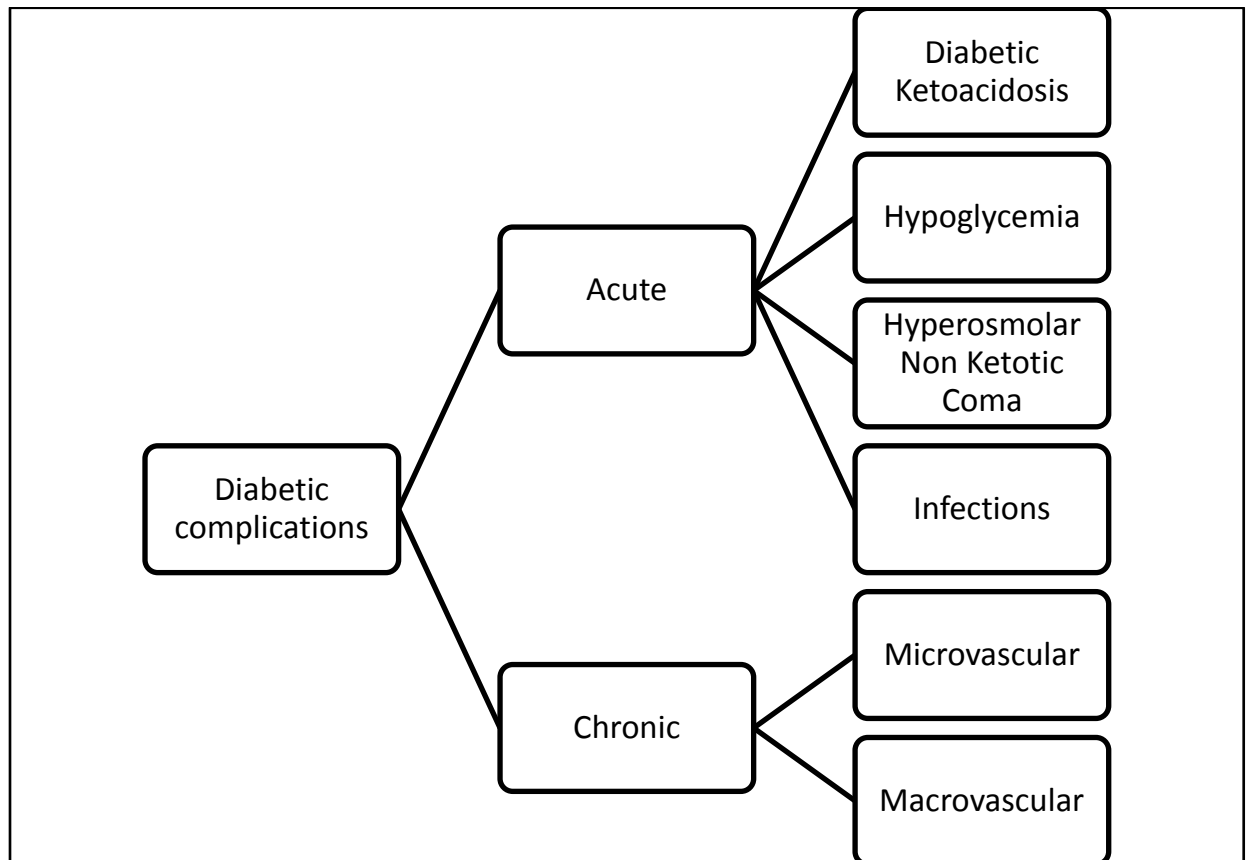
Reference: (30)

Diabetic ketoacidosis (DKA) is more commonly seen in those with type 1 diabetes. DKA is a clinical condition characterized by high sugars, presence of metabolic acidosis and high amount of total ketone bodies in the blood. This commonly occurs due to discontinuation of insulin. Factors linked to discontinuation of treatment include financial constraints, feeling unwell, depression, no access to insulin, alcohol and substance abuse (31).

Hypoglycemia is a condition in which blood sugars fall to less than 60mg/dl. The symptoms may vary from dizziness and palpitation to loss of consciousness. In the USA studies have shown that the number of hospital visits due to hypoglycemia is 0.054 per patient per year. The greatest risk of developing hypoglycemia was seen in those who used insulin. The next group of people who were at a risk of developing hypoglycemia were those who used sulphonyureas. Those on biguanides and thiazolidinediones were not at an increased risk of hypoglycemia. The people who had experienced hypoglycemia were at a higher risk of discontinuing their medication. It was also found that they had a higher all cause expenditure and diabetes related expenditure than those who did not. They spent an extra US$5024 on overall health care and an extra US$3747 on the treatment of diabetes (25).

Hyperosmolar non ketotic coma is more commonly seen inthose with type 2 diabetes mellitus.

Infections such as respiratory (30) and periodontal infections (32) are more common among people with Diabetes. People with diabetes are more prone to have pneumcoccal pneumonia, cavitatory lesions in tuberculosis and periodontal disease. The link between periodontal disease and diabetes is a long one. It has been shown that treating periodontal disease also helps in glycemic control. Chronic hyperglycemia has been shown to result in angiopathy. Endothelial cells which from the inner lining of blood vessels do not depend on insulin for glucose uptake. When blood sugars increase endothelial cells increase their amount of glucose uptake. Thisresults in an increase in the amount of surface glycoproteins they produce subsequently increasing the thickness of their basement membranes.

This results in weakening of the endothelial lining thus causing angiopathy (33).

Micro-vascular complications include retinopathy, nephropathy and neuropathy. Macro-vascular complications include cerebro-vascular accidents, myocardial infarction and peripheral vascular disease (26).

A study in the Netherlands was done to study predictors for micro and macro vascular complications in people with diabetes. In all 563 people from 5 different Dutch hospitals were studied. The mean age group among the study participants was 68 and the mean duration of diabetes among them was 13 years. They had a median HbA1c of 7.5%. This study found that age, duration of diabetes, renal function, gender, atrial fibrillation and skin auto fluorescence were independently associated with macrovascular complications (34). Autofluorescence is defined as the natural emission of light from biological structures.Skin autofluorescence measures the amount of advanced glycation end-products, which increase in Diabetes mellitus (35).

3.2 Challenges Related To Diabetes And Its Treatment

3.2.1 The Growing Epidemic:

Several studies have been done around the world to estimate the global prevalence of diabetes mellitus. One such study published in 2010 used estimates from 91 different countries and predicted a prevalence of 7.7% by the year 2030; an increase of 69% in developing countries and 20% in the developed countries (36). Though the problem of diabetes mellitus is increasing in all continents it is growing fastest in India (20). The number of Indians living with diabetes in the year 2000 was 32 million and the International Diabetes Federation estimates that this number will rise to 69.9 million by 2025.

The Chennai Urban Rural Epidemiology Study (CURES) 2004 found that the crude prevalence of diabetes was 15.5% among adults aged 20 years and above with an age standardized prevalence of 14.3%. The burden of the disease was equal among both genders. This study also studied the prevalence of diabetes related complications. They found that the prevalence of vascular complications among those with diabetes was as follows: diabetic retinopathy 17.6%, diabetic nephropathy 2.2% and the prevalence of microalbuminuria was 26.9% (2).

The Chennai Urban Population Study compared the prevalence of coronary artery disease among diabetics and non-diabetics and their findings were as follows:

	Diabetics	General population
Coronary artery disease	21.4%	9.1%
Peripheral vascular disea	6.3%	2.7%

Studies done in rural India too have documented an increase in the prevalence of diabetes. The rate of increase in diabetes is 2.02/1000 population per year. The rate of increase in the prevalence of diabetes among men was found to be 3.33/1000 population per year and was greater than that among rural women, 0.88/1000. It was also found that there is a larger prevalence of impaired glucose tolerance and impaired fasting glucose among south Indians as compared to north Indians (37). The increase in prevalence of diabetes is of great concern as 70% of those with diabetes die due to cardiovascular diseases (37).

3.2.2 Compliance to the Treatment of Diabetes:

Compliance is an issue which has been growing in importance as it was realized that despite the health care providers' best efforts treatment objectives remained unmet due to non-compliance to therapy. Since the 1970's a lot of research has been done on this issue. Through many studies it was found that compliance to long term treatment was only 40-50% and compliance to short term treatment was higher- 70-80%. Compliance to life-style modifications (including diet and exercise) was only 20-30%. Non-compliance can occur due to many factors and in many ways (38).

Types of non-compliance (38):

Non-compliance to treatment is a problem that can present in different ways .After reviewing literature available to date Jin et al have compiled a list of different ways in which non-compliance can occur.

Receiving a prescription but not filling it.

1.   Taking an incorrect dose

2.   Taking medication at the wrong times

3.   Increasing or decreasing the frequency of doses

4.   Stopping the treatment too soon

5.   Delaying in seeking healthcare

6.   Non-participation in clinic visits

7.   Failure to follow doctor's instructions

8.   "Drug holidays", which means the patient stops the therapy for a while and then restarts the therapy.

9.   "White-coat compliance", which means patients are compliant to the medication regimen around the time of clinic appointments

 Numerous factors have been found to affect compliance. "Hard Factors" are the quantifiable factors that affect compliance to therapy, such as, cost of treatment, therapy related adverse effects, accessibility to health care services and satisfaction to treatment. "Soft factors" include unquantifiable factors namely attitude towards treatment, motivation and beliefs (38).

Table 3.4: Factors affecting compliance

Category	Factors
Patient-centered factors	Demographic Factors: Age, Ethnicity, Gender, Education, Marriage Status
	Psychosocial factors: Beliefs, Motivation,Attitude
	Patient-prescriber relationship
	Health literacy
	Patient knowledge
	Physical difficulties
	Tobacco Smoking or alcohol intake
	Forgetfulness
	History of good compliance
Therapy-related factors	Route of administration
	Treatment complexity
	Duration of the treatment period
	Medication side effects
	Degree of behavioral change required
	Taste of the medication
	Requirements for drug storage
Healthcare system factors	Lack of accessibility
	Long waiting time
	Difficulty in getting prescriptions filled
	Unhappy clinic visits

Social and economic factors	Inability to take time off work
	Cost and Income
	Social support
Disease factors	Disease symptoms
	Severity of the disease

Reference: (38)

Compliance and adherence to treatment has also been found to be affected by "diabetes fatalism." Diabetes fatalism is defined as "a complex psychological cycle characterized by perceptions of despair, hopelessness and powerlessness."(39). A study done in South Carolina, USA showed that there was a significant association between diabetes fatalism and poor compliance, poor knowledge of diabetes and poor adherence to lifestyle modification. Many institutions have looked into factors affecting compliance to the treatment of diabetes mellitus. One such hospital based study done in Saudi Arabia revealed a non compliance rate of 67.9% among their patients (40). Some of the risk factors were:

(1)   male sex (OR=1.9, 95%CI 1.32 -4.57)

(2)   residing in an urban area, (OR=5.21, 95%CI 3.65- 8.22)

(3)   being illiterate (OR= 5.27, 95%CI 4.63- 7.19)

(4)   Non adherence to exercise (OR=5.55, 95%CI 4.26- 6.00)

The Canary Islands is an area where the mortality associated with diabetes is unusually high. A study looking at compliance to treatment in this region revealed that 48% of the men and 28% of the women did not follow the treatment as advised. Seventy five percentage of the women were found to have sedentary lifestyles and 54% of them were

obese. Dietary intake was measured in this population and it was found that 95% of them consumed large amounts of saturated fats (41).

A study done in a tertiary care centre in Kolkata in 2011 showed a poor compliance rate in 67.8% of their patients. They did not find age, sex or presence of co morbid conditions to be a risk factor for non-compliance. They however did find that housewives were at a greater risk of non-compliance. Those who had petty businesses had a higher compliance rate. This difference was suggested to be due to financial dependence among housewives and financial independence among those who had their own businesses. There was a significantly higher rate of compliance among those who had a good knowledge of diabetes mellitus (42).

3.2.3 The cost of treatment of diabetes:

An important aspect of diabetes is the occurrence of complications. Studies in 1998 showed that the cost of treatment of diabetes increases in the presence of diabetes related complication. A patient with diabetic foot may increase his expenditure on health care from Rs. 4510 per year to Rs. 7200 per year.

It has been found that the expenditure on health care increases once a person has diabetes and increases further if the person develops complications related to diabetes. A study done in UAE in 2010 brought to light the impact of diabetes on the direct costs of health care. An individual with diabetes spent US$1,605/- per year on health care which was 3.2 times greater than the per capita expenditure on health care among those without diabetes. Direct costs on health care increased 2.2 times among those with micro vascular

complications, 6.4 times among those with macro vascular complications and 9.4 times among those with micro and macro vascular complications.

Direct expenditure on hospitalization increased too. In those with micro vascular complications it increased by 3.7 times. Among those with macro vascular complications alone it was higher by 6.6 times and was five times higher among those with macro and micro- vascular complications (43).

3.3 Strategies to combat the problem of Diabetes

3.3.1 Prevention of diabetes mellitus:

A Cochrane review of 8 trials studying the benefit of diet and exercise in preventing diabetes among those with impaired fasting glucose and impaired glucose tolerance showed that there was no conclusive evidence to show that either of these methods was useful in preventing diabetes mellitus type 2. They were not found to be useful in combination as well (3).

3.3.2 Interventions to improve compliance to therapy:

Non-compliance is a complicated problem seen in many people with chronic diseases. In the United States of America there is a large burden of non compliance and it amounts to a financial burden of 1 billion US dollars annually on the health care system. Many interventions have been studied to improve compliance to treatment. A Cochrane review of all interventions revealed the following results. Some studies involved interventions to improve the compliance to medical advice and some interventions targeted both patients and health care providers.

Interventions provided by nurses:

One intervention studied by Mease et al was the impact of educational classes along with weekly nurse visits in the form of telemedicine consultation. The control group received conventional care. When the two groups were compared the intervention group was found to have significantly lower Hba1c (0.4%). However technological problems were faced as the trial was being conducted (4).

Another trial studied the benefits of "motivational interviewing and "problem solving treatment". In this trial the control arm received intense counseling sessions from nurses. Each participant received 6 individual sessions of 30 minutes each and 3 monthly booster sessions via telephone. The participants in the control arm received brochures on the treatment of diabetes. They measured change in the risk scores of type 2 diabetes and cardiovascular risk factors as the primary outcome. The secondary outcome measured was the cost effectiveness and change in lifestyle. At the end of the trial it was found that the intervention was not useful as the attendance to each of these sessions was low.

Home Aid interventions:

Another trial studied the impact of more intensive care. The participants in the intervention arm received mailed packets (including contact details of their physician, danger signs of diabetes and scheduled appointment dates) a booklet on the management of diabetes and regular home visits by health aides in the event of missed appointments. They were compared against a control group that received usual care. It was found that there was an average decrease of 10.1mg/dl in fasting blood sugars in the intervention group as opposed to an increase of 5.1mg/dl in the control group. Also, the interventional group had 12% more contacts with their doctors and visited the ophthalmologist more regularly (2).

Diabetes education intervention

Various studies assessing the impact of diabetes education on the change in HbA1c showed no difference between control and intervention arms (4).

Patient participation:

Patient participation programmes were compared against regular consultations with the physician. The outcomes that were measured included HbA1c, cardiovascular events, LDL and blood pressure. It was found that there was a significant reduction in each of these parameters in both arms.

Studies involving patients in goal setting have shown that though collaborative goal setting is not directly associated with better sugar control it is associated with better self efficacy (44).

At the end of the review of 21 trials on interventions to improve compliance the authors concluded that none of the interventions were useful, however they also had no adverse effects. Also the need for more research on interventions to improve adherence is needed

A complete package for diabetes care:

Diabetes mellitus is associated with microvascular and macrovascular complications and all follow up programmes aim at glycemic control and prevention of complications. The Geisinger Health Plan (GHP) proposed a bundle management of diabetes including 9 components. Studies showed that individuals receiving treatment by the GHP had lower risk of developing diabetes related complications (45).

Table 3.5: Components on the bundle management protocol of the Geisinger Health Plan

HbA1c	Should be measured every months
Target HbA1c	<7%
LDL	To be measured yearly
Target LDL	<100mg%
Blood pressure	<130/80
Urine protein testing	To be done annually
Influenza immunization	To receive the vaccine every year
Pneumococcal immunization	To receive one dose before the age and one dose after
Smoking status	Patient should have stopped smoking

Source: thehealthplan.com

3.4 National Programmes to control the problem of Diabetes Mellitus

National Diabetes Control Programme:

In view of the rising prevalence of diabetes among Indians the Government of India launched the National Diabetes Control Programme (NDCP) (46).This was initiated during the VII Five year plan as a pilot project in a few districts in Tamil Nadu, Karnataka and Jammu and Kashmir with the following objectives:

1.   Prevention of diabetes through identification of high risk subjects and earlyintervention in the form of health education

2.   Early diagnosis of disease and appropriate treatment morbidity and mortality withreference to high risk group

3.   Prevention of acute and chronic metabolic, cardiovascular, renal and ocular complication of the disease

4.   Provision of equal opportunity for physical attainment and scholastic achievement for the diabetic patients

5. Rehabilitation of those partially or totally handicapped diabetes people.

However, due to lack of funds, this programme was not expanded. In 2004 the Integrated Disease Surveillance Programme (IDSP) was initiated. This was to focus on infectious disease and screening of non communicable diseases. Screening was done by assessing anthropometry, physical activity, measuring blood pressure, screening for use of tobacco and assessing nutrition However the IDSP focused only on screening individuals for the presence of high risk factors. There was no interventional component (47).

In 2005 the National Rural Health Mission (NRHM, 2005-2012) was launched. It aimed at the prevention and control of communicable diseases and non communicable diseases. Its core strategy was "developing capacities for preventive health care at all levels for the promotion of healthy lifestyles and reduction I consumption of tobacco and alcohol" (47).

Under the 9[th]five year plan (2007-2012) another programme was started to control the problem of non communicable diseases. This is the National Programme for the Prevention and Control of Diabetes, Cardiovascular disease and Stroke. This too is being launched in a phased manner (47).

3.5 Terms And Definitions

Compliance: Patients behavior in terms of taking medication, following diet or executing lifestyle changes coinciding with the health care provider's recommendation for health and medical advice.

The question of "what is *good* compliance" is a never ending debate. But researchers have agreed that 80% to 120% compliance is good. In this study all those with more than 80% compliance to pills have been classified as compliant

Overall compliance: In this study overall compliance was the highest rate of compliance to ay one drug.

Adherence: The ability and willingness to abide by a prescribed therapeutic regime.

Good glycemic control: As per ICMR guidelines, those with a HbA1c of less than 7 were classified as people with good glycemic control.

Good Knowledge of prescription score: Those who scored more than or equal to 7 in the knowledge of score questionnaire were considered to have good knowledge.

Regular attendance: Those who had missed their last visit were classified as irregular and those who had gone for their last appointment were classified as regular.

4. METHODOLOGY

4.1 The Study design:

A community based cross sectional study

4.2 The study area:

The study was conducted in the Kaniyambadi block of Vellore district, Tamil Nadu. This is a rural developmental block which consists of 82 villages and has a population of over 1.10 lakhs. (Source: 2010 Census by the Dept. of Community Health, CMC, Vellore).

The health care facilities available in the area include 3 government primary health care centers, one government tertiary care hospital, multiple small private clinics and the health care provided through the CHAD (Community Health and Development) program of the Department of Community Health and the multi-specialty hospital of CMC, Vellore.

For the last 30 years, the CHAD program has been providing primary and secondary health care in the Kaniyambadi block through its peripheral team and a 120 bedded secondary care base hospital. The peripheral health care team consists of 17 health aides, 5 public health nurses and 3 doctors. One health aid is assigned to a population of 5000 (3-4 villages) to carry out the following duties: registering births, deaths, marriages, newly pregnant women, eligible couples, identifying people who need medical attention and to provide basic health education. The

public health nurse is assigned to take care of a population of 20,000 and is trained to provide basic health care to pregnant women, post natal women, neonates, patients with diabetes and hypertension and to identify people who need special medical attention.

4.3 The doctor –run clinic:

Every village is visited by a doctor run clinic once a month. The team members include one MD Community Medicine post graduate student, one intern, one public health nurse one health aid and one driver. At each clinic all antenatal women, sick children and people with diabetes, hypertension and other chronic illnesses are seen and managed as per established protocols.

Patients suspected with diabetes mellitus are referred to the base hospital. Blood investigations are done at the base hospital and if the patient is confirmed to have diabetes the patient is provided with a chronic disease card on which the advised medications and the blood results are noted. Once a month this patient visits the doctor run clinic, with this chronic disease card, where he/she is examined and given drugs for a month. Once in 3 months is the diabetics are advised to visit the base hospital to have their blood sugars tested. Based on the results, the doe of the oral hypoglycemic agents is titrated. Patients with diabetes are also advised to have regular opthalmological examination for diabetic retinopathy once a year and to have a serum creatinine measured once a year.

The doctor- run clinic has many advantages. As the team runs the clinic in the village the patient has no travel expenses and incurs no loss of wages. He/she is

44

also able to see the doctor free of charge. The patients' socioeconomic status is evaluated by the health aide and the public health nurse and the cost for the investigations and treatment depend on the affordability of the patient.

At the periphery, the drugs are dispensed by the public health nurse under the supervision of a doctor who instructs them on the frequency and dosage of the drugs.

4.4 Study Participants:

Inclusion criteria:
Any permanent resident of Kaniyambadi block, who
 (1) Has been diagnosed with type 2 diabetes at least one year before
(2) Is on treatment with OHAs and
 (3) Is over the age of 30 years.

Exclusion criteria:

(1) Patients on insulin

(2) Patients who are bedridden

4.5 Sampling and sample size calculation:

Prevalence of compliance was estimated to be 50% (38).

N= $4pq/d^2$

N= $\dfrac{4 \times 50 \times 50}{10 \times 10}$

Thus, sample size was calculated to be 100.

Selection of participants:

All patients with diabetes are registered in the CHAD health information system (HIS). The first 57 patients were recruited from the routine monthly peripheral clinics and the remaining 43 were randomly recruited by using the list of diabetics available in the CHAD HIS.

4.6 The questionnaire:

A standardised back translated questionnaire was used to collect general demographic data.

Parameters measured for each participant	Method used
Knowledge of prescription	Standardised knowledge of prescription questionnaire
Diet intake	24 hour diet recall
Level of physical activity	WHO Global Physical Activity Questionnaire
Glycemic control	HbA1c
Adherence to oral hypoglycaemic agent	Pill count

4.6.1 Global physical Activity Questionnaire.

This questionnaire was created because of the need to have a standardised method of measurement of exercise all across the world. It reliability and validity was measured by testing it in 9 different countries. It was compared against an accelerometer. The reliability was found to be good. Spearman's rho was 0.67 -0.81 and Kappa was 0.67-0.73. But the criterion validity was only 0.06 –0.35, similar to other tools (48).

4.6.2 Methods of measuring drug compliance:

There are various methods of measuring drug compliance. The direct measure includes blood tests to measure the serum level of the drug. Indirect measure include patient self-reporting, pill counts, pharmacy dispensing records and electronic monitoring – which is considered the gold standard for measuring drug compliance. But the method chosen for each study must depend on the type of study done and the possible inferences that are to be made (49).

A study was conducted in Boston in 1999 to compare patient reporting; pharmacy reporting and pills count against electronic monitoring, which is considered the gold standard of measuring drug compliance. It was found that pill counts had a moderate agreement with the electronic monitoring. Patient reporting of adherence was found to be poor and a lot of misclassification was noticed. However patient's reporting of non-adherence was reliable and valid (50).

In settings with financial restriction the use of pill counts along with patient self reporting has been found to be as useful as electronic monitoring (51). Another study done among African-American smokers, to estimate the adherence to the drug Varenicline using three different methods- pill counts, self reporting and a visual analog scale revealed that estimating pill counts were the most valid technique with a sensitivity of 88% (95% CI = 75.0-95.0) and a specificity of 80% (95%CI = 30.0-99.0) as compared to the gold standard (plasma measurement of Varenicline)(52).

In this study, conducted in Kaniyambadi block, pill counts were for every participant by doing home visits.

Every participant has a self retained chronic disease card on which the details of the last visit, clinical findings and treatment details are noted. The *expected* number of drugs was calculated using the information from the chronic disease card. The *observed* number of drugs was recorded by counting the actual number of pills that were with the patient. Drugs bought from outside were also taken into account. Compliance was measured by calculating the percentage of pills that were consumed. A compliance rate of more than 80% was classified as 'good compliance' for the study.

4.6.3 Haemoglobin A1c measurement:

A sample of venous blood, measuring 2ml, was collected from every participant at the time of the interview and the sample was transported to the Clinical Biochemistry laboratory at the Christian Medical College, Vellore within 24 hours. Haemoglobin A1c was measured using the HPLC method with the Bio-Rad Variant 2.

4.6.4 Assessing Dietary intake:

Methods of measuring dietary intake:

Dietary intake may be measured using various methods.

1.   24 hour diet recall: in this method the participant is asked to list out all food items consumed over the last 24 hours

2.   Food frequency score: different food types are listed e.g. cereals, pulses, green leafy vegetables, nuts and oils, meat etc. The participant is asked how frequently in a week each of the food items is consumed: once a week, twice a week or every day.

3.   Weighment method: in this method the interviewer is to spend the entire day in the participants house and must measure the actual weight of the food consumed and take into account the wastage as well.

In this study, the dietary intake was measured using the 24 hour diet recall method. Each participant was asked to list out all food items and beverages consumed over the last 24 hours with the quantity consumed. The measurements were made with spoons, cups and bowls which were already measured. If they had consumed a food items not listed in the National Institute of Nutrition (NIN,

Hyderabad) they were asked to list all the ingredients of the dish. A person who had consumed coffee or tea was asked to specify the amount of sugar in the beverage. All the listed food items were converted into kilocalories using guidelines published by NIN, Hyderabad.

3.6.5   Knowledge of prescription score:

Each participant was asked to identify their tablets and correctly state the dose and frequency in which it was to be taken. A person on only one drug would be asked 3 questions and those on 2 and 3 drugs had to answer each of these questions for each drug they were taking. So each person had a different number of responses. Their scores were all converted into a score out of 10. And those with a score of more than or equal to seven were classified as people with good knowledge of prescription.

3.6.6   Measuring the Socioeconomic status:

The socioeconomic status of each participant was measured using the Modified Kuppusamy scale for 2012. The per capita income, educational status and their occupation was used to calculate the score and based on the Modified Kuppusamy scale they were classified into lower and middle class.

4.7 Data entry and analysis:

All the data was entered using EpiData3.1. Data analysis was done using SPSS 17.0. For each participant the caloric intake, level of physical activity, compliance rate and knowledge of prescription was calculated. For the entire study population the prevalence of good glycemic control, the prevalence of sedentary lifestyle and the average caloric intake was calculated. The correlation between each of the individual factors (drug compliance, physical activity and caloric intake) and glycemic control was measured.

 A multiple logistic regression was done to measure the independent impact of each of these variables on the glycemic control (HbA1c).

5. RESULTS

5.1 Demographic description of the study population:

The 100 participants were selected from 22 different villages. The size of the clusters varied from 1to 9.

5.1.1 Sex distribution of the study subjects:

Table 5.1 Distribution of participants according to sex

Sex	Frequency	Percentage
Male	26	26%
Female	74	74%
Total	100	100%

Women formed the major portion of the study population, 74% of the total.

Figure 5.1: Age distribution among the participants
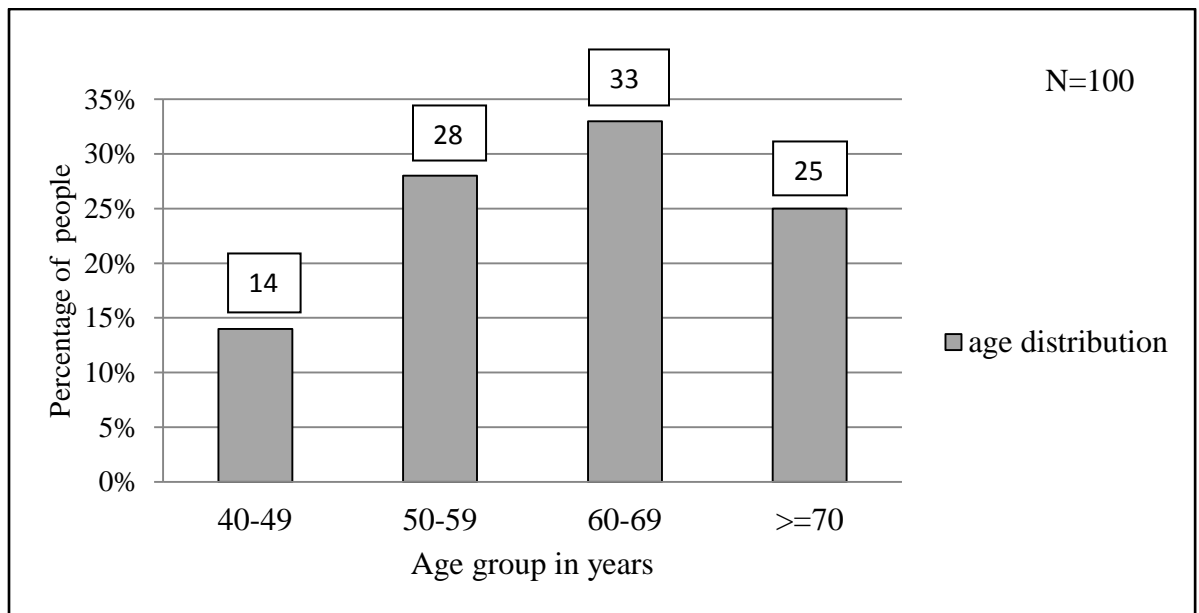
The age of the participants varied from 40 to 85.The mean age of participants was

60.36 years with a standard deviation of 10.2 years.

5.1.3 Occupation:

Table 5.2: Distribution of occupations of the study subjects

Occupation	Frequency	Percentage
Unemployed	21	21%
Housewife	24	45%
Manual/Agricultural Labourer	19	19%
Skilled Labourer	12	12%
Petty Shop Owner/Cultivator	16	16%
Salaried and pensioners	8	8%
Total	100	100%

A majority of the study participants were involved in household work. Nineteen percent were involved in either manual or agricultural labour and 21% of the study population was unemployed.

Figure 5.2 Gender-wise distribution of occupation
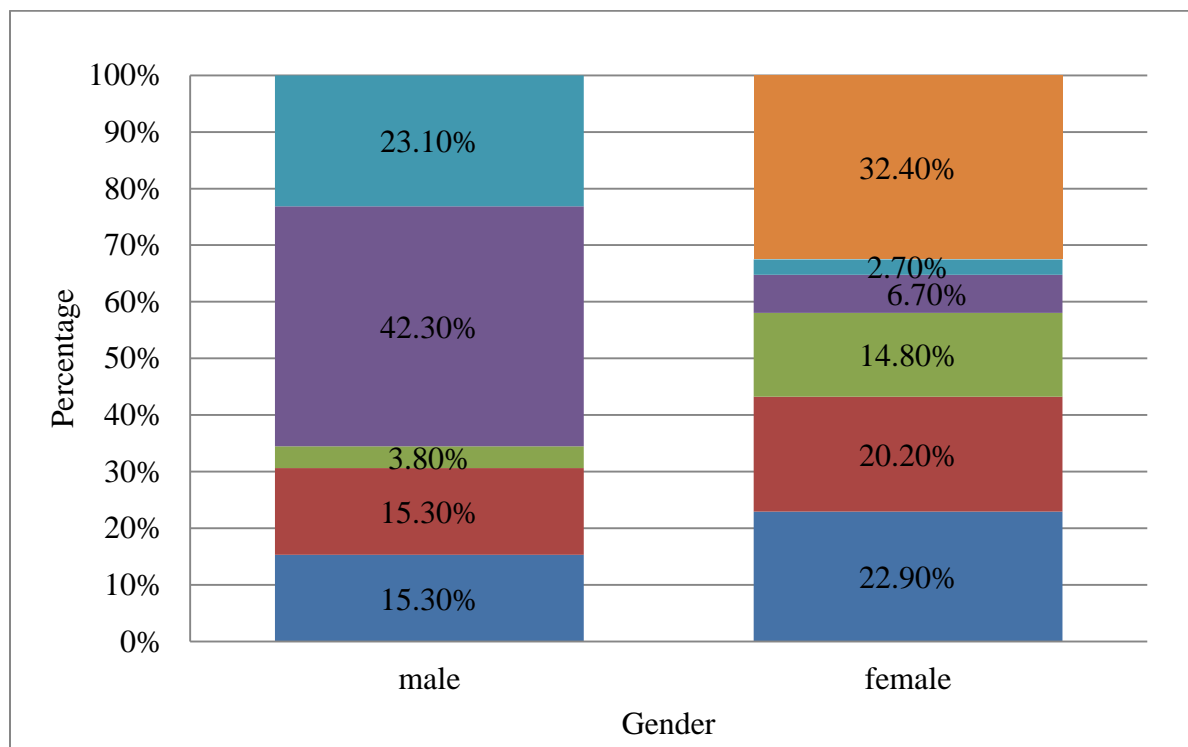
Among the women 32.4% were involved in household work, 20.2% were involved in manual or agricultural labour and 22.9% of them were unemployed.

Among the men 42.3% were either shop owners or cultivator owners. A larger proportion of men had salaried jobs or received pension (23.1%) when compared to women (2.7%). As compared to women fewer men were unemployed.

5.1.4 Socioeconomic status as measured by Modified Kuppusamy Scale:

Figure 5.3: Distribution of socioeconomic status of participants
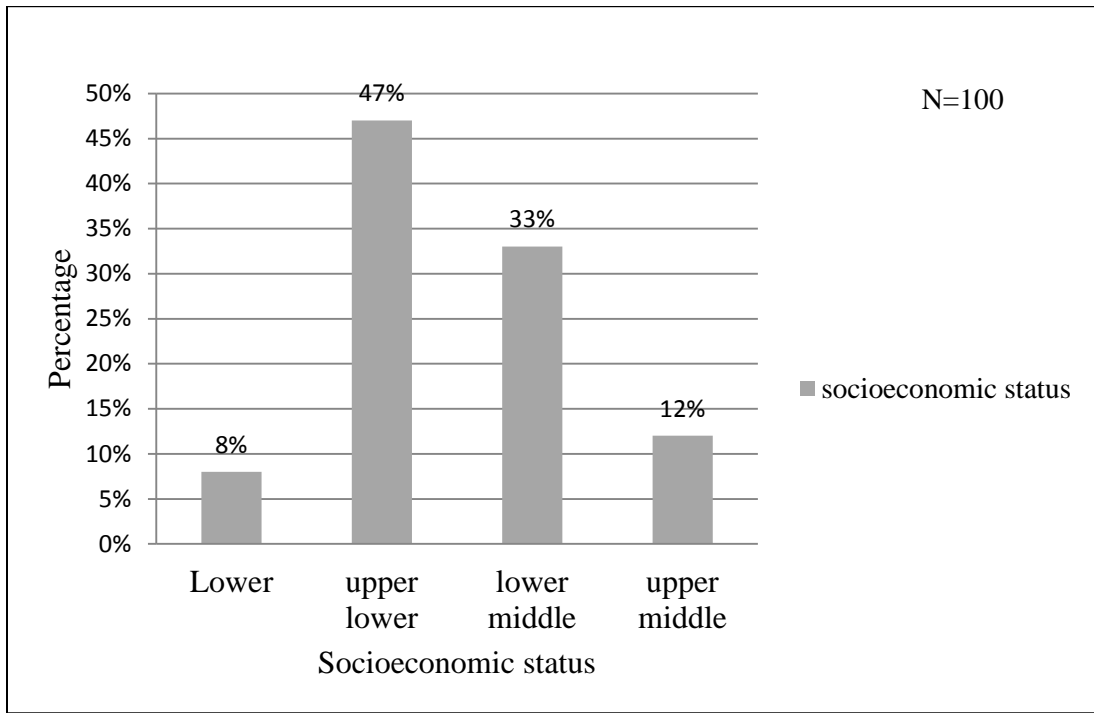
Fifty five percentage of the participants were from the lower socioeconomic group and 45% from the middle socioeconomic group.

5.2 Lifestyle and behavior:

Use of alcohol and tobacco:

Table 5.3: Current use of alcohol/ tobacco

Current Use Of Alcohol/tobacco	Frequency	Percentage
Yes (use alcohol or tobacco)	5	5%
No (neither use alcohol nor tobacco)	95	95%
Total	100	100%

Out of the 100 participants only 5 gave history of using tobacco or alcohol.

5.3 Medical History:

5.3.1 Time since diagnosis of diabetes:

The time duration since diagnosis was estimated for each participant and it varied from 1 to 20 years. The mean duration since diagnosis of diabetes was 5.46 years and the interquartile range was 2-7 years.

Table 5.4: Mean number of years since the diagnosis of diabetes

Age group in years	Mean years since diagnosis of diabetes
40-49	4.1
50-59	4.5
60-69	6.6
>=70	5.76

The above table shows that with increasing age, duration since diagnosis of diabetes is increasing which is expected in chronic diseases.

5.3.2 Co-Morbid Conditions present among participants:

Out of the 100 participants 30% had no co morbid conditions, 50% had only one co morbid condition and the remaining 20% had 2 co morbid conditions. The most common co-morbid condition was hypertension.

Figure 5.4: Types of co-morbid conditions
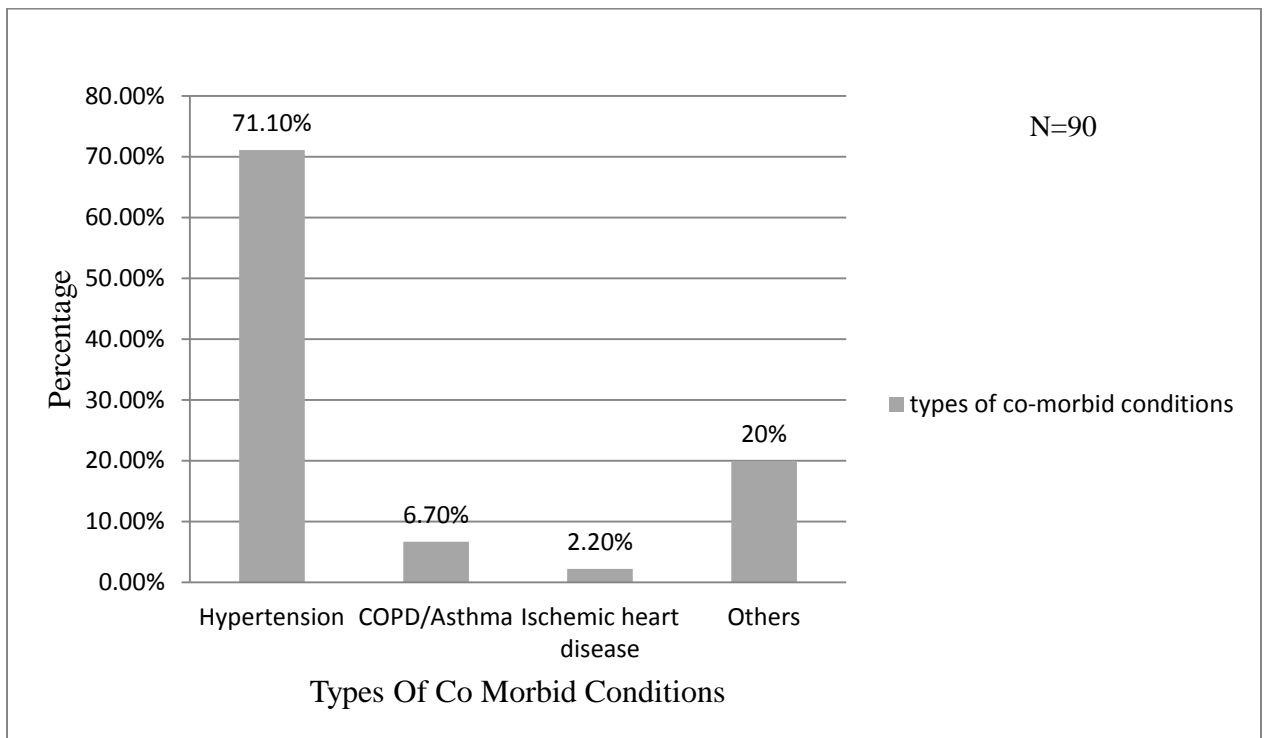
5.3.3 Drug combinations prescribed:

Figure 5.5: Various Drug combinations prescribed to the participants
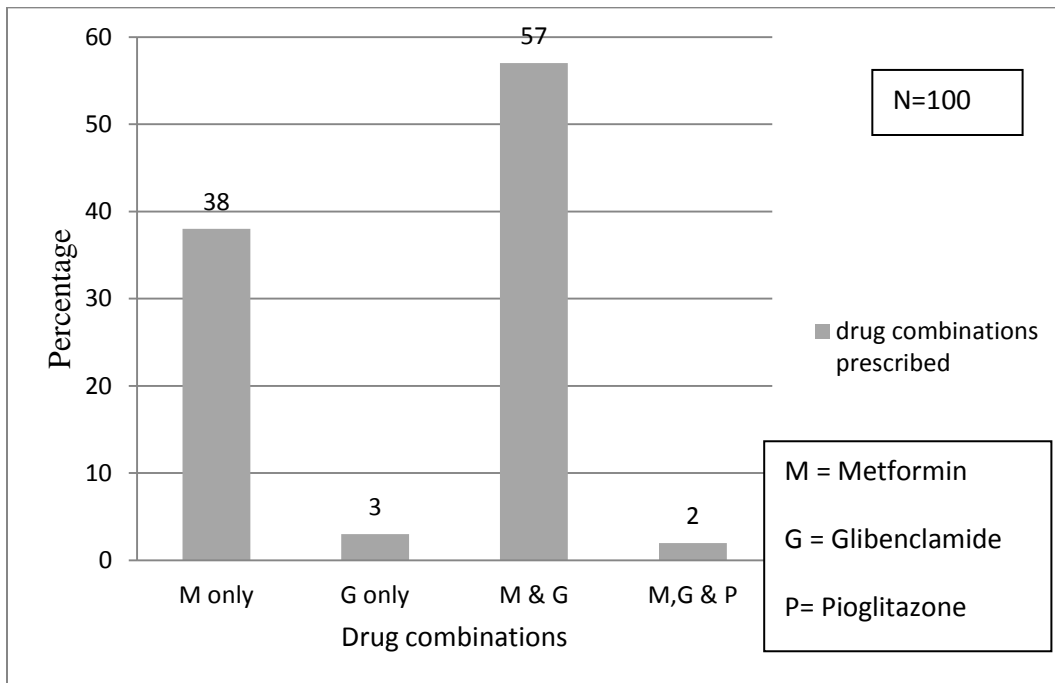
Metformin was the most commonly used oral hypoglycemic agent and was used in combination with glibenclamide for 57% of the participants.

5.3.4 Number of pills per day

Figure 5.6: Distribution of pill load per day among participants
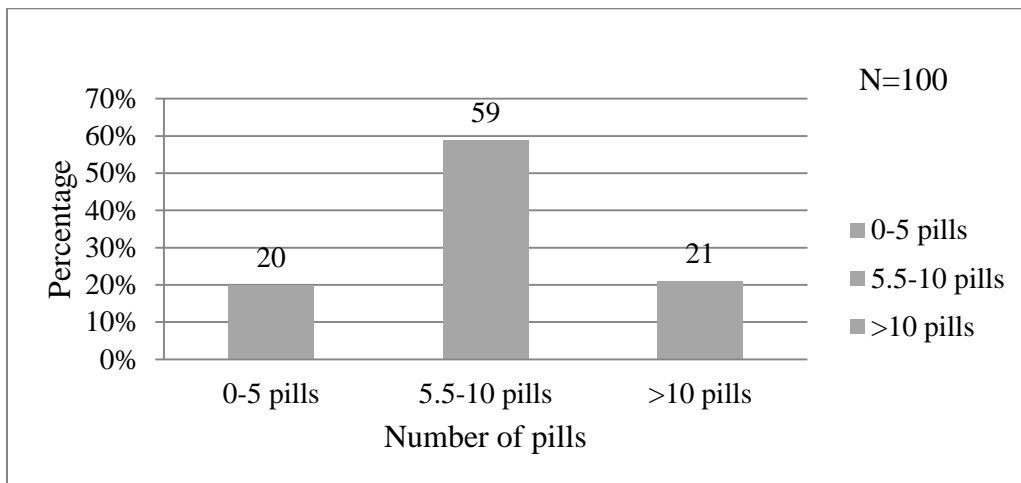
From each person's chronic disease card the number of drugs with their dosage and frequency was noted and the total number of pills the patient was advised to take per day was estimated

Many of the patients had co morbid conditions and were on more than one drug. The pill load varied from 2 to 16 pills per day. The average number of pills prescribed to the patients was 8.024 per day.

5.3.5 Occurrence of adverse effects due to OHAs:

Figure 5.7: Occurrence of side effects due to oral hypoglycemic agents
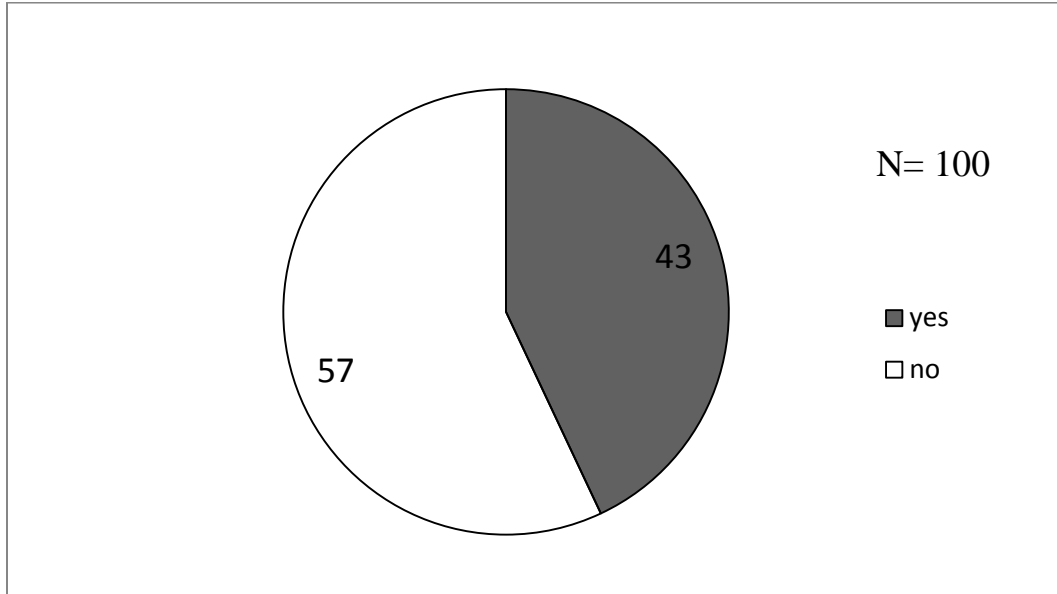
Patients on treatment for diabetes experienced side effects due to the oral hypoglycemic agents. Out of the 100 participants 57 experienced no side effects. Out of the remaining 43 participants 35 had one side effect and 8 had 2 side effects.

Types of side effects due to OHAs:

Figure 5.8: Types of side effects experienced
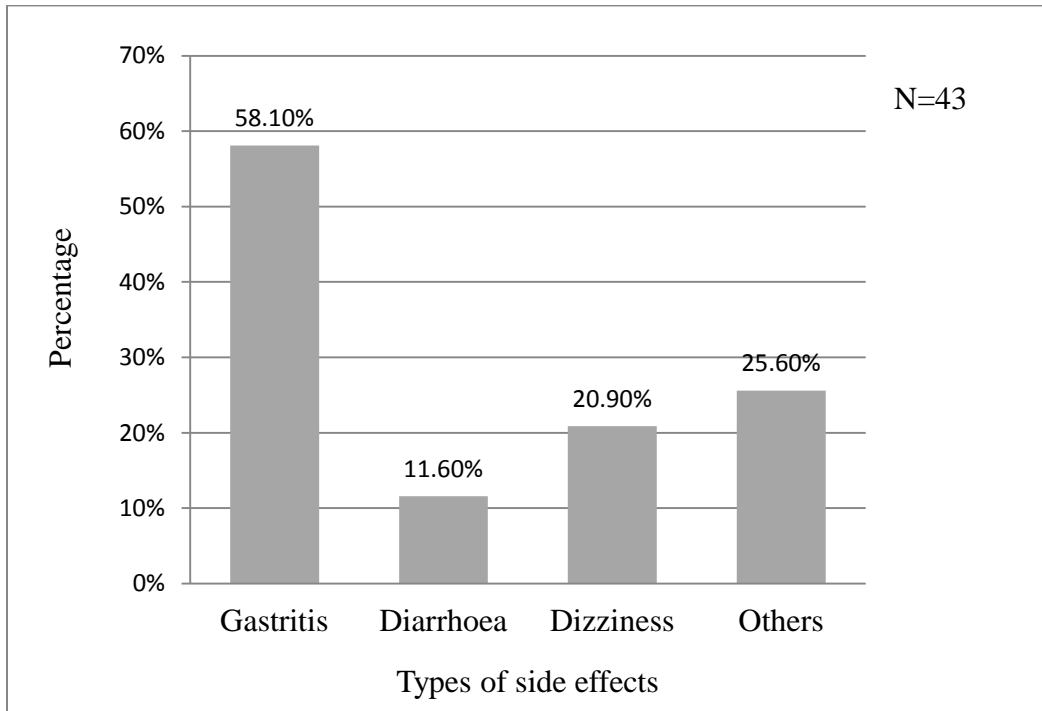
The most common side effect was gastritis.. Out of the 43 people who had experienced side effects, 58.1% had gastritis, 11.6% had diarrhoea and 20.9% had dizziness. Some of the "other" side effects experienced were fatigue, constipation, headache and feeling of tension

5.3.6 Patient incurred cost for medication:

Figure 5.9: Patient incurred cost per month
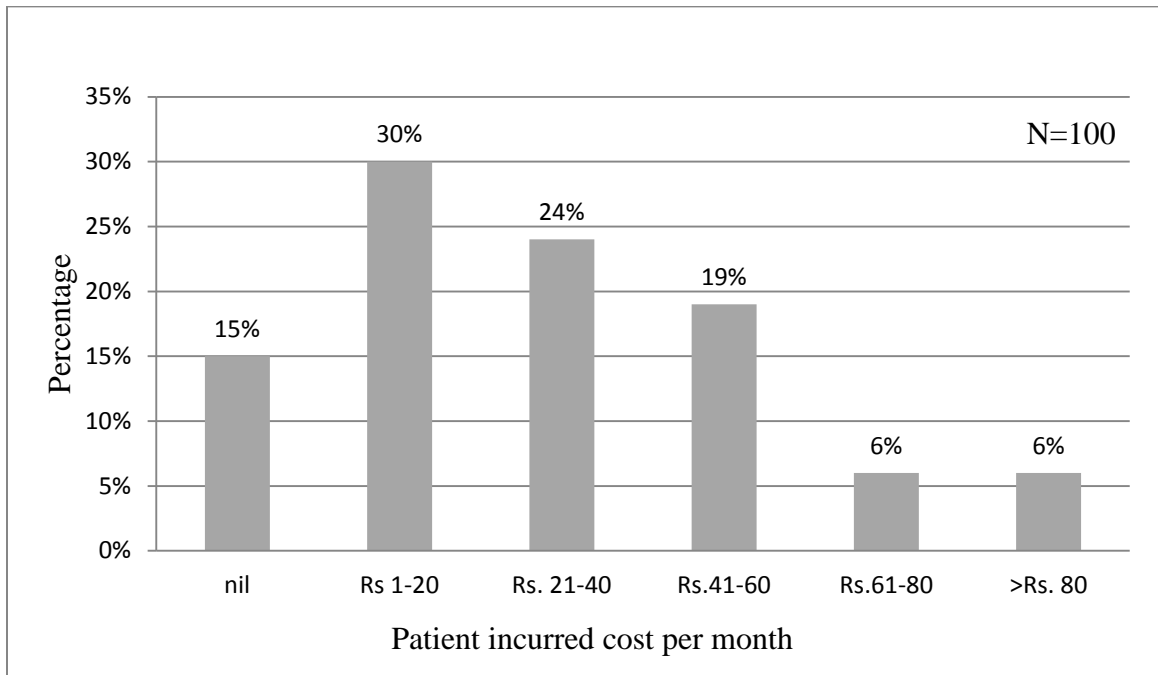
The amount on money spent per month on drugs varied. The above graph shows that 15% of the participants received treatment that was free of cost. An average of Rs. 34.34 was spent on medication.

This difference in the amount spent on medication is because each patient's socioeconomic status is assessed and they are expected to pay only what they can afford.

5.4 Knowledge of prescription score:

Figure 5.10: Distribution of knowledge of prescription score
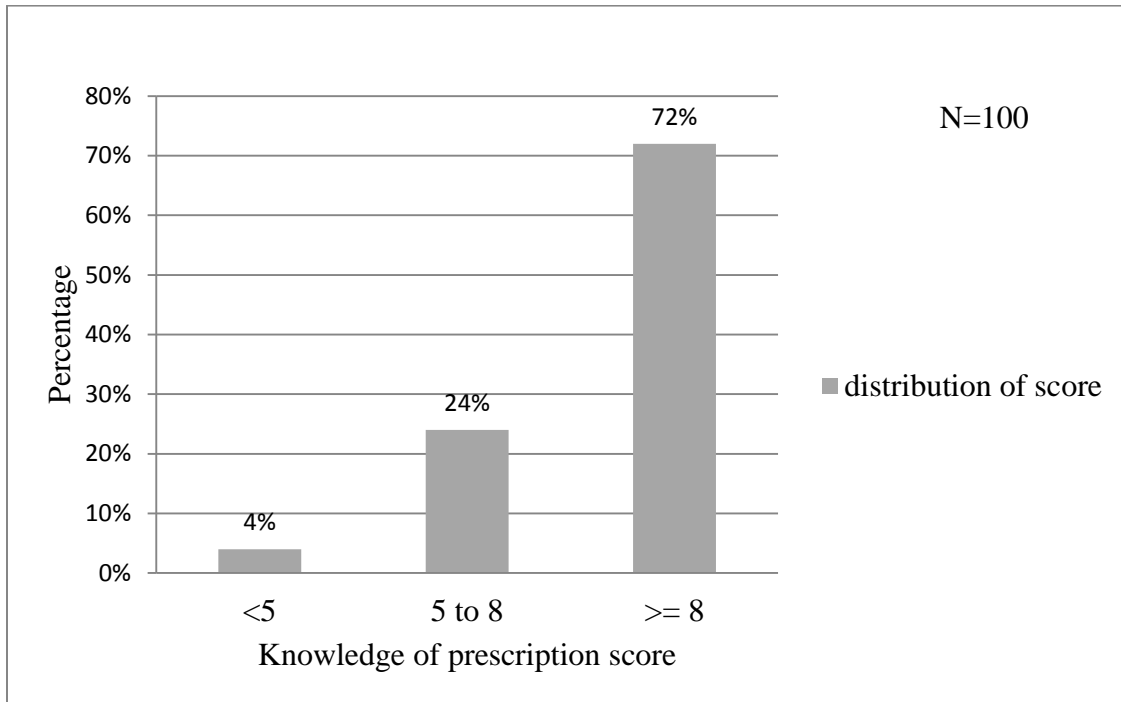
Each participant was asked to identify their OHA's and state the dosage and frequency at which the drug was prescribed by their doctor. For every correct answer the person was awarded a score of one and these scores were converted to a scale of 10. A large proportion of the subjects (72%) were able to correctly identify their tablets and state the prescribed dose and frequency.

5.5 Lifestyle:

5.5.1 Diet intake:

Figure 5.11: Distribution of daily total calorie intake
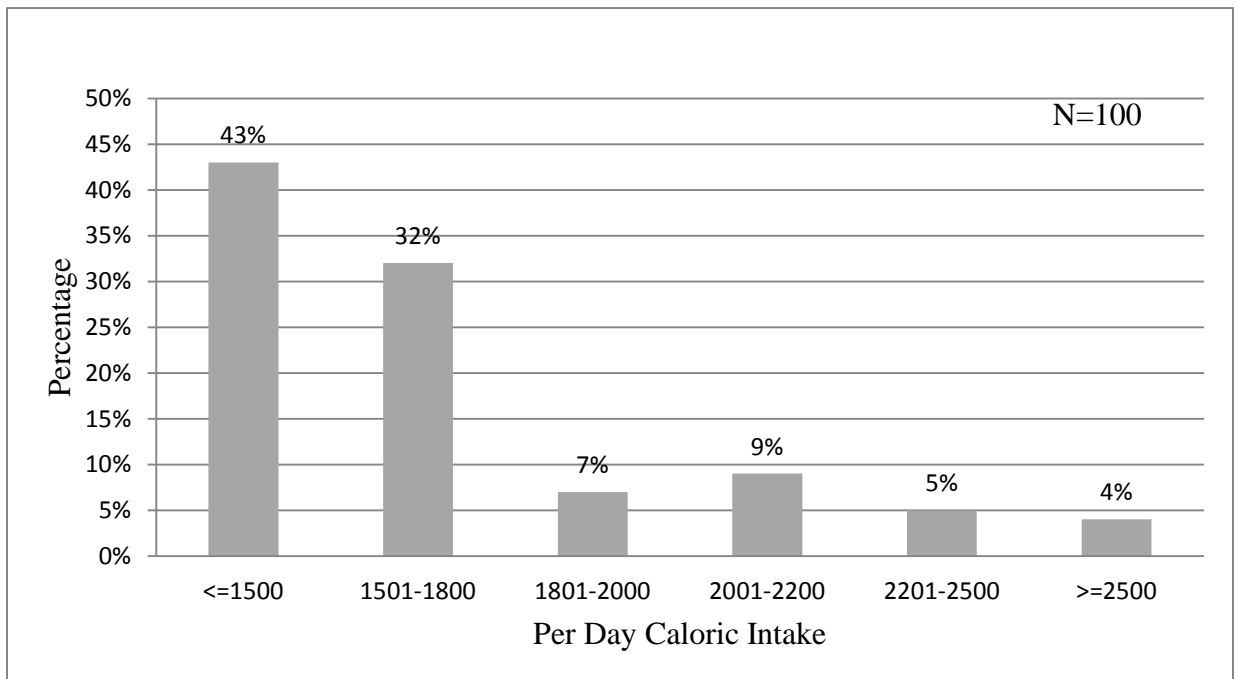
Each participant's diet intake was measured using a 24 hour diet recall and converted into calories using standards prescribed by the National Institute of Nutrition, Hyderabad.

The daily caloric intake ranged from 704.25 to 5419.30 Kilocalories.

The mean caloric intake per day was 1614.83 Kcal with a 95% Confidence Interval of 1494.6 -1735.1 Kcals and standard deviation of 601.2 Kilocalories.

Figure 5.11 shows the distribution of calorie intake among the men and women. Out of the 26 men, 50% of them consumed less than 1800 kcals per day and out of the 74 women, 84.6% of them consumed less than 1800 kcals per day.

Figure 5.12: Distribution of caloric intake among men and women.
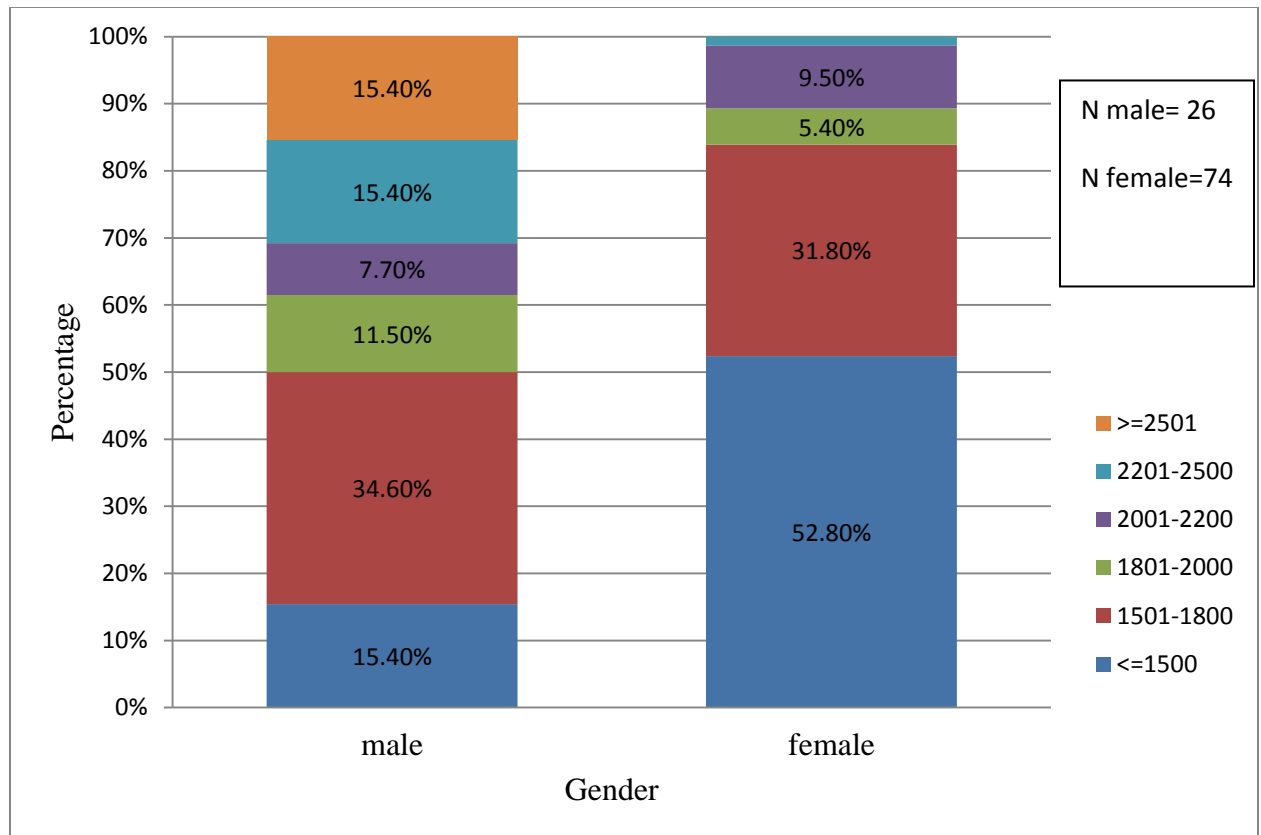
Out of the female participants 52.8% consumed less than 1500kcal per day and another 31.8% of them consumed 1500-1800kcal per day.

Out of the 26 men 15.4% were consuming less than 1500kcal per day, 34.6% consumed 1500-1800 kcal and 11.5% consumed 1800-2000 kcals.

5.5.2 Physical Activity:

Table 5.5: Percentage of people involved in each type of activity

Type of activity	% of People involved	% of people not involved
Vigorous intense activity	10	90
Moderately intense activity	17	83
Walking/ using cycle for transport	86	14
Recreational activity	1	99

The above table shows that 10 people out of 100 were involved in vigorous intense activities,like carrying heavy weights and climbing stairs or inclined slopes, which cause increase in heart rate or respiratory rate.

Seventeen out of 100 were involved in moderate intense activities,like carrying small weights, which cause increase in heart rate or respiratory rate.

Overall 25 people out of 100 were involved in either vigorous or moderate intense activity.

Out of 100 participants 84 either walked or used a bicycle for transport for at least 10 minutes in a day.

Only 1 person was involved in moderately vigorous recreational activities.

Each person was questioned on involvement in each type of physical activity (vigorous and moderate intense activity at work and during recreation) and the amount of time spent relining or resting. The number of days and minutes spent per day in each of these activities was also measured. As per the GPAQ protocol these responses were all clubbed together and reclassified. So each person,based on the overall time spent on each type of physical activity, was classified as a person with a sedentary lifestyle, moderately active lifestyle or a highly active lifestyle.

Figure 5.13: Levels of overall physical activity
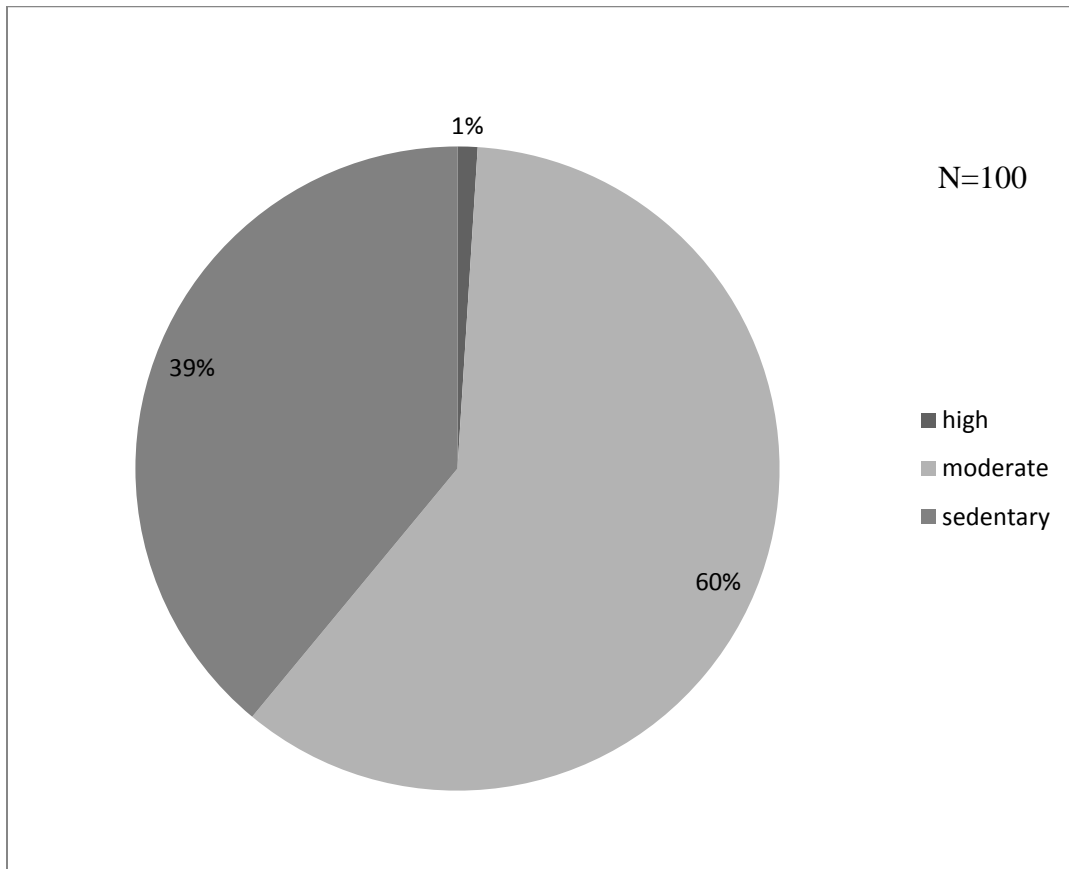
Only one male participant fell in the category of high activity. Thirty nine percent of the participants were leading a sedentary lifestyle.

To validate this tool 10% of the sample population was interviewed by the public health nurses.

The results are given below:

Table 5.6: Observed agreement among the observers while using the Global physical activity questionnaire

Findings of the principle investigator

		Low activity	Moderate activity	High activity
Findings of the public health nurses	low activity	2	3	0
	Moderate activity	0	1	0
	High activity	0	4	0

Table5.7: Expected agreement among the observers

Findings of the principle investigator

		Low activity	Moderate activity	High activity
Findings of the public health nurses	low activity	2	3	0
	Moderate activity	0	1	0
	High activity	0	4	0

Observed agreement = 30%

Expected agreement= 18%

Kappa statistic= (observed agreement- expected agreement)/ (100- expected agreement)

Kappa= 14.6%

This concludes that there was poor agreement between observers while using this tool.

5.6 Glycemic control as assessed by HbA1c

Figure 5.14: Distribution of HbA1c levels among the study participants
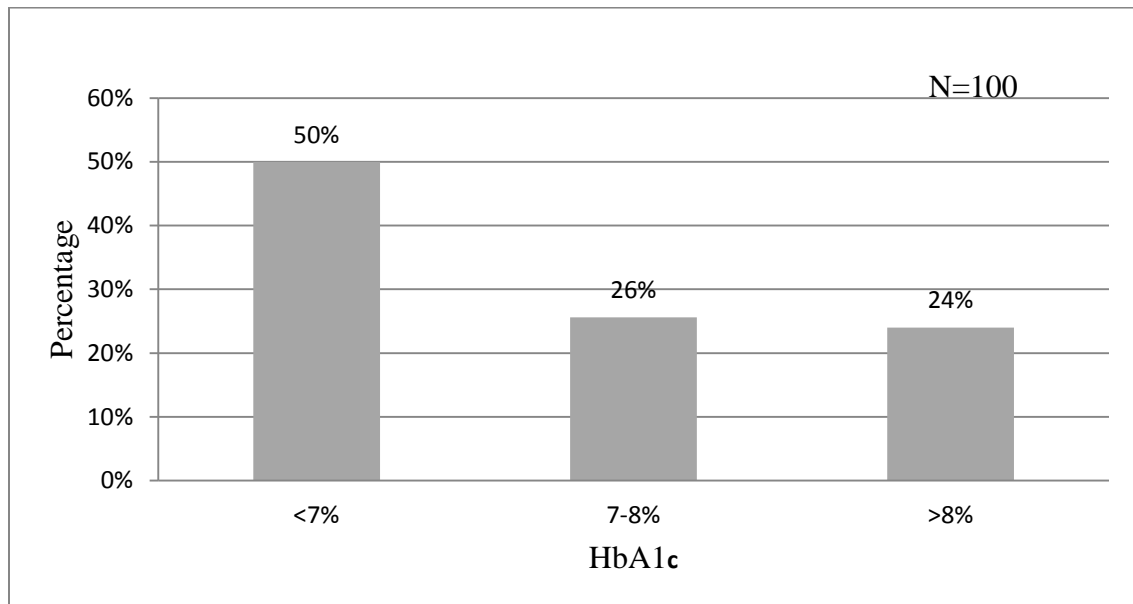
The values of HbA1c ranged from 5.2 to a maximum of 12.1%.. The mean HbA1c was 7.3 % with a 95% confidence interval of 7.024-7.576. According to the ICMR guidelines of 2005, 48.8% of the study population had ideal glycemic control, 25.6% had satisfactory glycemic control and 25.6% had unsatisfactory control.

5.7 Compliance rates to OHAs:

Table 5.8: Compliance to OHAs

Compliance rate	Metformin	Glibenclamide
<50%	28.9%	17%
50-79%	34.0%	17%
>=80%	37.1%	66%

5.7 Correlations And Associations

5.7.1 Correlation between HbA1c and Daily total calorie intake:
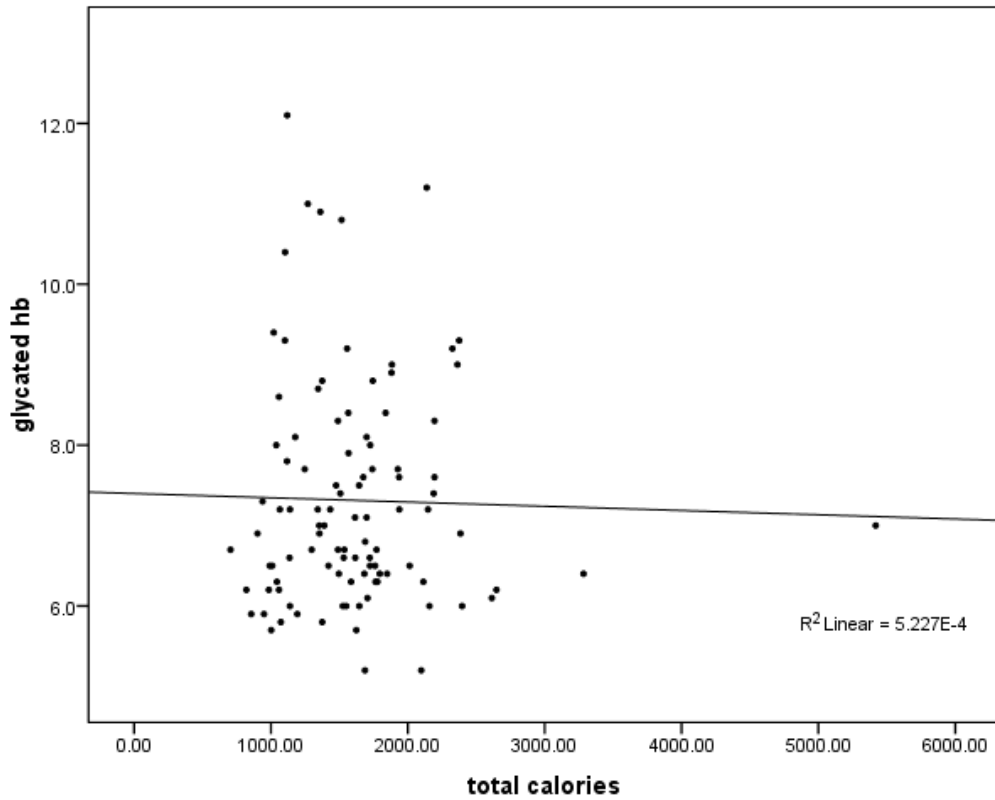
The Pearson's correlation co-efficient was -0.023 with a significance value (2 tailed) of 0.821 and this finding was not statistically significant.

5.7.2 Correlation between HbA1c and compliance to drugs

All participants were classified into the following groups:

- compliant to 2 drugs (n=12),

- compliant to 1 drug (n=52) and

- not compliant to any drug (n=36)

The mean HbA1c was calculated for each of these groups:

Figure 5.15: Mean HbA1c versus compliance to OHAs
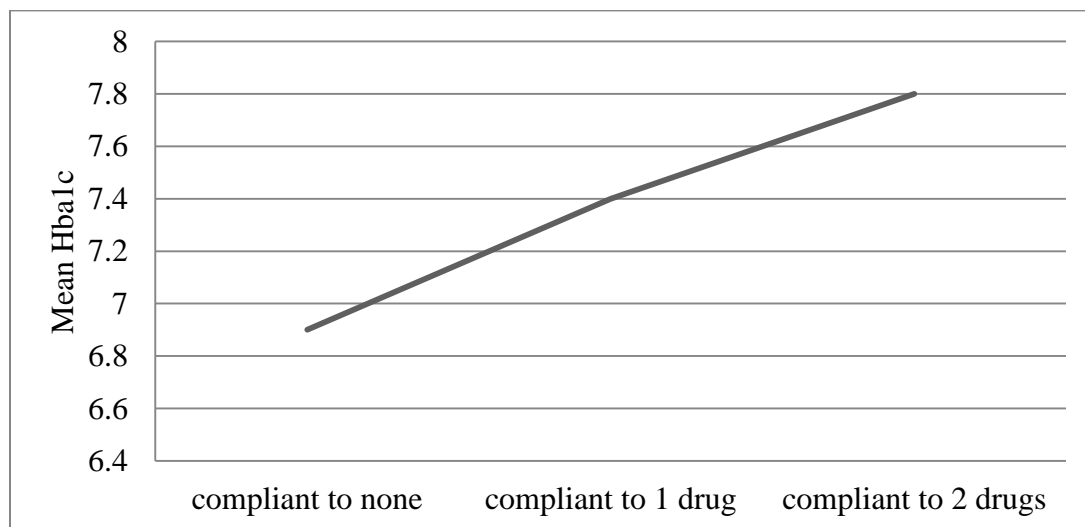
Figure5.15 shows that those who are noncompliant to 2 drugs have the best glycemic control. Those with poor glycemic control are commonly advised 2 drugs. Unless they take these tablets continuously for a period of time their sugars will not be controlled. This factor is not portrayed through this graph.

Figure 5.16: Correlation between HbA1c and adherence to glibenclamide
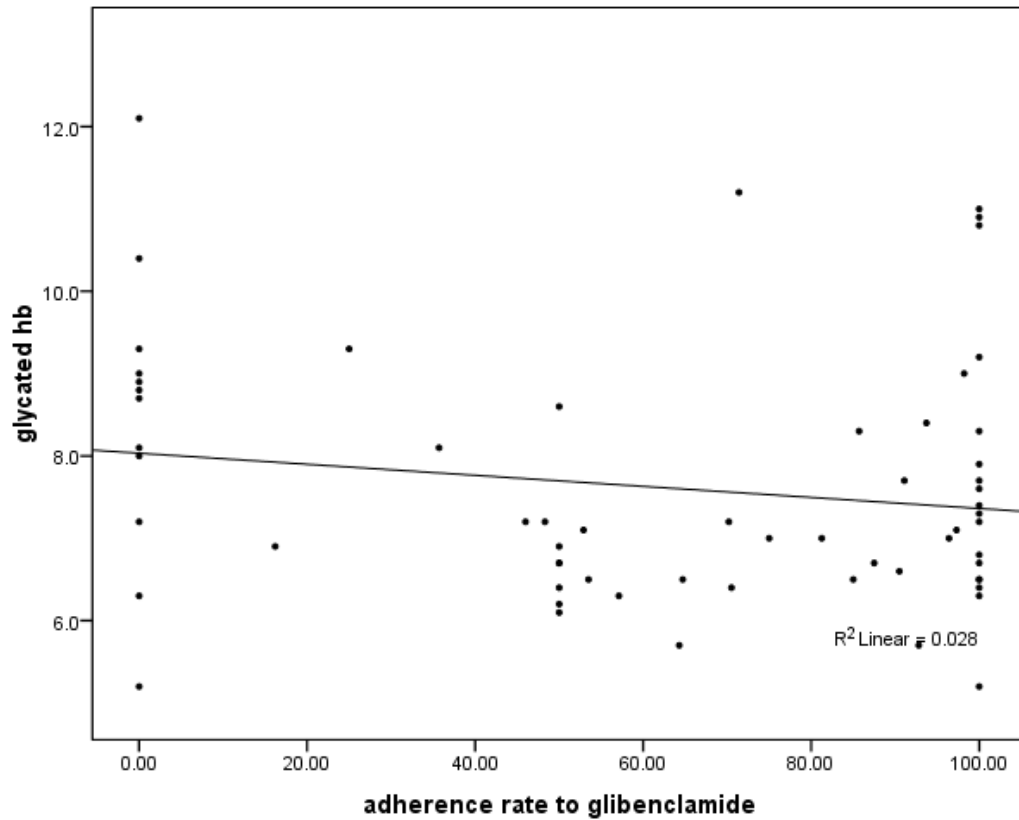
The Pearson's correlation co-efficient was -0.168 suggesting that as adherence increases HbA1c decreases. However, this finding was not statistically significant as indicated by the significance value of 0.192.

Figure 5.17: Correlation between HbA1c and adherence to metformin
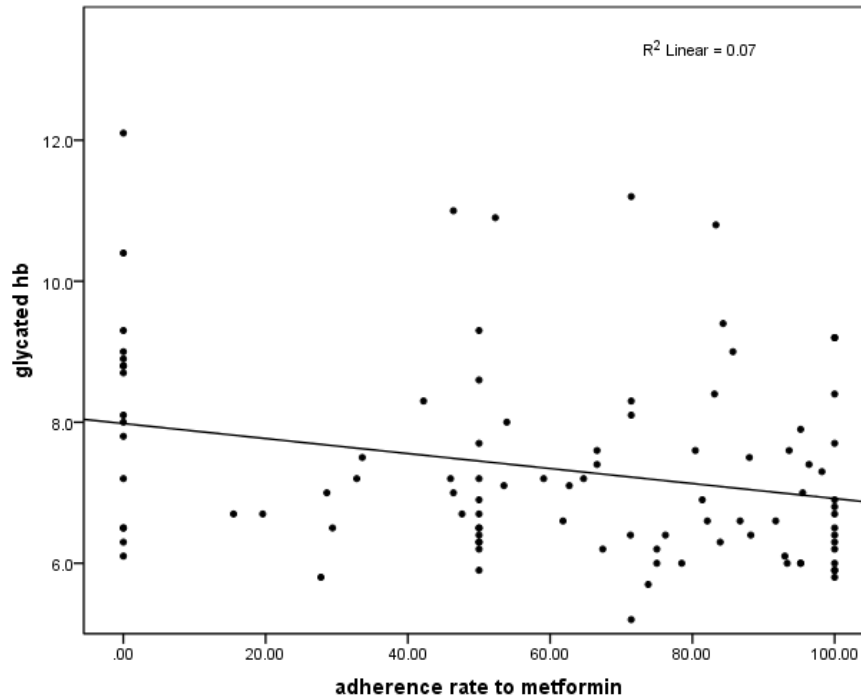
1.	2.	adherence rate to metformin	glycatedhb
adherence rate to metformin	Pearson Correlation	1	-.264[**]
	Sig. (2-tailed)		.009
	N	97	97
glycatedhb	Pearson Correlation	-.264[**]	1
	Sig. (2-tailed)	.009	
	N	97	100

**. Correlation is significant at the 0.01 level (2-tailed).

The correlation co-efficient was 0.264 which shows a 26.4% correlation between adherence to metformin and HbA1c and this was statistically significant.

Figure 5.18 Correlation between HbA1c and Overall adherence to OHAs.
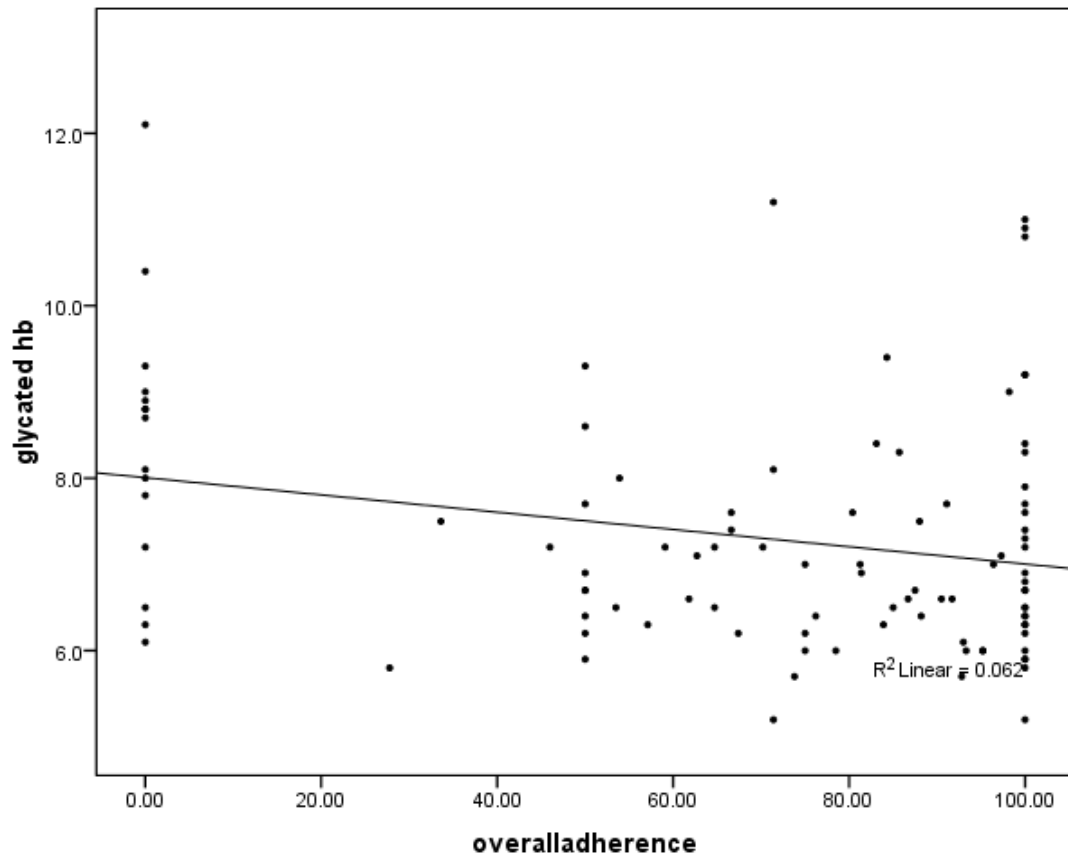
Overall adherence was calculated for each person by calculating the maximum adherence to any one pill. The Pearson's correlation co-efficient was -0.248 with a 2 tailed significance value of 0.013. This means that there is a 24.8% correlation between overall adherences and HbA1c and this correlation is significant.

Figure: 5.18: Correlation between HbA1c and number of years since diagnosis:
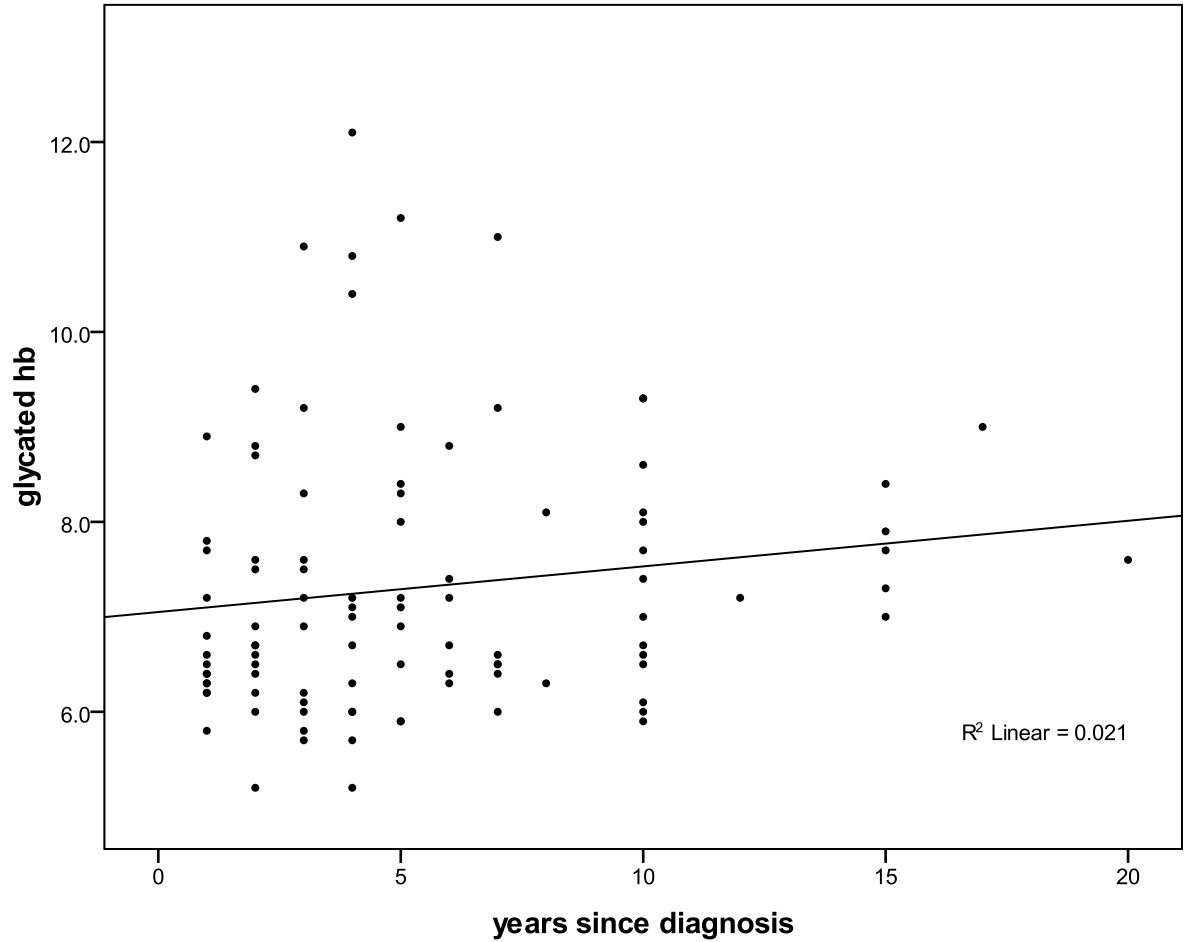
The Pearsons' correlation coefficient for this was 0.144. This means there is a 14% correlation between glycated hemoglobin and years since diagnosis; however this finding was not statistically significant with a p value of 0.154.

5.7.3 Association between physical activity and glycemic control

Based on the level of physical activity the participants were divided into 2 categories: those who were sedentary and those who had moderate or high level of physical activity. The mean HbA1c of each of these groups were calculated and compared.

Table 5.8: Group Statistics mean HbA1c versus level of physical activity

	sedentary	N	Mean	Std. Deviation	Std. Error Mean
Glycatedh b	sedentary	39	7.238	1.2671	.2029
	mod/high level	61	7.361	1.4697	.1882

To measure if this observed difference between the 2 groups was significant an independent sample t-test was done.

Table 5.9: Independent samples t-test

	Levene's test for equality of variances		t- test for Equality of means				
	F	significance	t	df	Significance (2 tailed)	Mean difference	Std. Error of difference
Equal variances assumed	0.375	0.542	-0.427	98	0.670	-0.122	0.286

Table 5.10: Results of t-test comparing physical activity and HbA1c

	Sedentary lifestyle		Moderate/ high level of activity		SE (95% CI)	p value
	mean	SD	mean	SD		
HbA1c	7.2%	1.26	7.3%	1.46	0.28(-0.068-0.044)	0.67

The standard error of difference between the 2 means was not significant. This means that there was no significant association between physical activity and glycemic control.

5.7.9 Glycemic Control among both genders:

Table 5.11: sex * controlled sugars Cross tabulation

		controlled sugars		
		High sugars	Controlled sugars	Total
Male	Count	10	16	26
	Expected Count	12.2	13.8	26.0
	% within sex	38.5%	61.5%	100.0%
female	Count	37	37	74
	Expected Count	34.8	39.2	74.0
	% within sex	50.0%	50.0%	100.0%
Total	Count	47	53	100
	Expected Count	47.0	53.0	100.0
	% within sex	47.0%	53.0%	100.0%

This two by two table shows that 38.5% of the male participants had poorly controlled sugars and 50% of the female participants had poorly controlled sugars (defined as HbA1c>=7%) in the study.

A chi square test was done to measure the difference between the two proportions revealed a Chi square value was 1.028 and p value was 0.311. This means that sex is not associated with poor glycemic control.

5.7.10 Level of knowledge of prescription and glycemic control:

Table 5.12 Level of knowledge of prescription * controlled sugars Cross tabulation

3.	4.		High sugars	Controlled sugars	Total
			controlled sugars		
Level of knowledge	Poor knowledge	Count	15	13	28
		Expected Count	13.2	14.8	28.0
		% within level of knowledge	53.6%	46.4%	100.0%
	Good knowledge	Count	32	40	72
		Expected Count	33.8	38.2	72.0
		% within level of knowledge	44.4%	55.6%	100.0%
Total		Count	47	53	100
		Expected Count	47.0	53.0	100.0
		% within level of knowledge	47.0%	53.0%	100.0%

This table shows that 53.3% of those with poor knowledge of their prescription had high blood sugars and 44.4% of those with good knowledge of their prescription had poorly controlled sugars. The Chi square test was done to test the significance of this difference. The Chi square value was 0.674 and the p value was 0.412. This means that the level of knowledge of the prescription is not associated with Glycemic control.

5.7.11 Socioeconomic score versus glycemic control:

Table 5.13 SES group * controlled sugars Crosstabulation

			controlled sugars		
			high sugars	controlled sugars	Total
SES group	low	Count	29	26	55
		Expected Count	25.9	29.2	55.0
		% within SES group	52.7%	47.3%	100.0%
	middle	Count	18	27	45
		Expected Count	21.2	23.9	45.0
		% within SES group	40.0%	60.0%	100.0%
Total		Count	47	53	100
		Expected Count	47.0	53.0	100.0
		% within SES group	47.0%	53.0%	100.0%

This table shows that 52.7% of those in the lower socioeconomic status group had poorly controlled sugars as opposed to 40.0% in the high socioeconomic group. The chi square test was done and the Chi square value was 1.609 with a p value of 0.205. This means that the socioeconomic status of the person is not associated with poor glycemic control.

5.7.12 Occurrence of side effects versus glycemic control:

Table 5.14 Experienced side effects * controlled sugars Cross tabulation

			Controlled Sugars		
			High Sugars	Controlled Sugars	Total
Experienced Side Effects	Yes	Count	22	21	43
		Expected Count	20.2	22.8	43.0
		% within experienced side effects	51.2%	48.8%	100.0%
	No	Count	25	32	57
		Expected Count	26.8	30.2	57.0
		% within experienced side effects	43.9%	56.1%	100.0%
Total		Count	47	53	100
		Expected Count	47.0	53.0	100.0
		% within experienced side effects	47.0%	53.0%	100.0%

This table shows that 51.2% f those who have experienced side effects and 43.9% of those who have no side effects have high sugars. The chi square test was done to see if this difference was significant. The Chi square value was 0.525 and the p value was 0.469. This means that the occurrence of side effects is not associated with poor glycemic control.

5.7.13 Physical activity versus glycemic control:

Table 5.15 Sedentary * Controlled Sugars Cross tabulation

			Controlled Sugars		
			High Sugars	Controlled Sugars	Total
Level of physical activity	Sedentary Lifestyle	Count	19	20	39
		Expected Count	18.3	20.7	39.0
		% within sedentary	48.7%	51.3%	100.0%
	moderate/high level of activity	Count	28	33	61
		Expected Count	28.7	32.3	61.0
		% within sedentary	45.9%	54.1%	100.0%
Total		Count	47	53	100
		Expected Count	47.0	53.0	100.0
		% within sedentary	47.0%	53.0%	100.0%

This table shows that 48.7% of those who lead sedentary lives and 45.9% of those who have moderate or high level of physical activity have poorly controlled sugars. The Chi square value was 0.076 and the p value was 0.783. This means that the level of physical activity is not associated with glycemic control.

5.7.14 Regular attendance versus glycemic control:

Table 5.16 Regular attendance * Controlled Sugars Cross tabulation

			Controlled sugars		
			High sugars	Controlled sugars	Total
Regular attendance	Yes	Count	36	51	87
		Expected Count	40.9	46.1	87.0
		% within regular attendance	41.4%	58.6%	100.0%
	No	Count	11	2	13
		Expected Count	6.1	6.9	13.0
		% within regular attendance	84.6%	15.4%	100.0%
Total		Count	47	53	100
		Expected Count	47.0	53.0	100.0
		% within regular attendance	47.0%	53.0%	100.0%

In the CHAD run Mobile clinic drugs are prescribed for only one month at a time.For every patient the each visit is documented in the patient retained chronic disease card. Those who had missed their last clinic were classified as 'irregular' and those who had not missed the previous clinic were classified as 'regular'. When the glycemic control of these two groups was compared, it was found that there was a significant association between clinic attendance and glycemic control. The Chi square value was 8.488 and the p value was 0.004. The Fisher's exact test was 0.006 (2- tailed significance).People who attended the mobile clinic regularly were having 7.8 times higher odds of having controlled blood

sugars as compared to those who did not attend regularly. (OR = 7.8, 95% CI 1.6 to 37.3).

Summary of the univariate analysis :

No.	Risk factor	Proportion of subjects with poor sugar control	Chi square value	p value
1.	Malegender	38.5%	1.028	0.311
2.	Poor Knowledge of prescription score	56.3%	0.674	0.412
3.	Low SES	52.7%	1.609	0.205
4.	Occurrence of Side effects	51.2%	0.525	0.49
5.	Sedentary Physical activity	48.7%	0.076	0.783
6.	Regular attendance at the mobile clinic	41.4%	8.488	0.004

5.8 Multiple Linear Regression

Association between selected exposure variables and the main outcome variable namely glycemic control as measured by Hba1c was carried out using multiple linear regression. The independent variables chosen were gender, level of knowledge regarding the drugs prescribed, SES, physical activity, overall adherence to OHAs and years since diagnosis of the disease.

88

	Unstandardized coefficient B	p value
Constant	7.119	
Gender (Female)	0.613	0.050
Level of knowledge of prescription (<70%)	0.206	0.496
SES (Low)	0.365	0.173
Level of physical activity (Sedentary)	-0.311	0.270
Overall adherence	-0.013	0.002*
Years since diagnosis	0.073	0.027*

This linear regression analysis shows that after adjusting for other factors, overall adherence and years since diagnosis of diabetes is associated with glycemic control.

For every 1% increase in adherence there is a 0.01% decrease in HbA1c and for every year that passes after the diagnosis of diabetes there is an increase in the HbA1c by 0.07%.

6. DISCUSSION

This is a cross sectional study which was designed to estimate the compliance rate to treatment of diabetes mellitus, the level of glycemic control, average caloric intake and level of physical activity and among patients attending the mobile clinic run by CHAD program of the Department of Community Health, CMC, Vellore.

6.1 Socio-demographic profile:

The study population consisted mostly of women. The timing of the mobile clinics is between 9 am and 5 pm and this could be one of the possible reasons for more women attending them at the villages, while the men tend to go outside for work. A majority of the participants were above the age of 60 and had been on treatment for diabetes for an average of 6 years. Fifty five percentage of the participants belonged to the low socioeconomic group and 45%were from the middle socioeconomic group.

  Out of the 100 participants 30 had no co morbid conditions, 50 had at least one co-morbid condition and 20 had 2 co-morbid conditions. Hypertension was the most common co morbid condition**.**

A study done in Kolkata in 2010 showed a similar demographic profile with 61% of their population being women and 61.07% of their population belonging to the 45-65 year age group (54).

6.2 Glycemic control:

This study assessed glycemic control by measuring HbA1c for all participants. HbA1c represents the average blood sugar levels of an individual over the last 3 months. So the glycemic control measured in the study is for a period of 3 months only. Using the ICMR set guidelines, 50% of the patients had 'ideal' blood sugars (HbA1c <7%) and 24% had very poor control of blood sugars (HbA1c >8%). Poorly controlled sugars have been found to be associated with poor cardiovascular outcomes and these 24% need to be further evaluated (28). When compared to some of the other studies done in India these results are comparable (53). Other Indian studies have shown a short term glycemic control of 37.7% and a long term glycemic control in only in 24% of patients (42). Studies done in Pakistan and Thailand also have shown lower rates of glycemic control 31.4% and 26.3% (53). Thus the problem of diabetes and maintaining good glycemic control is a challenge in most countries around the world.

The glycemic control in the Kaniyambadi population seems to better than that found in other settings. Individual factors that affect glycemic control are discussed below in order to possibly explore this difference.

. **6.3 Caloric intake:**

The calorie intake varied from 750 kcal per day to 2800 kcal per day. In this study caloric intake was measured by a 24 hour diet recall. As the body mass index was not measured, the ideal calorie requirements could not be estimated and hence the calorie excess or deficit could not be studied. However a rough estimate can be made. Out of the 100 participants 75% had a calorie intake of less than 1800. A Cochrane review of randomized controlled trials have shown that diet restriction cause a reduction in glycated hemoglobin but there insufficient studies to show the benefit in terms of the reduction in the risk of developing micro and macro-vascular complication (54).

6.4 Level of physical activity:

This study was done in a rural area where agriculture is the main source of income. In this study, 60% of the participants were involved in either moderate or high levels of physical activity on a regular basis. This finding is similar to the findings seen among diabetics attending a tertiary care center in Kolkata, where the prevalence of sedentary lifestyle is around 37.4% (42).

6.5 Compliance to drugs:

Pill counts were done at home for all 100 participants and it was found that 52% of participantsshowed an adherence of >80% to at least 1 drug.Studies from India have shown different levels of compliance varying from 11.3% to 33.2% (42). Some studies have shown that housewives are at a higher risk of non-compliance for financial reasons as they are not economically independent (42). In Kaniyambadi block, we see that economic status of the family is not a risk factor for poor glycemic control and the main reason for this could be that the treatment is subsidized depending on the affordability of the individuals.

But compliance does not depend only on financial status and is a combination of many other factors. In Kaniyambadi block the compliance may be higher because the mobile clinic visits the village regularly thus improving the individual's access to health care. This more available and accessible form of health care may be the contributing factor to the better level of glycemic control measured in this study.

6.6 Risk factors for poor glycemic control:

In this study, the various risk factors studied were compliance to medication, level of physical activity, socioeconomic status, gender, knowledge of prescription, occurrence of side effects, regularity of attendance at the mobile clinicand total calorie intake. Overall compliance to medication and regular attendance at the mobile clinic showed a statistically significant association with good glycemic control.

After adjusting for the presence of other factors, a multivariate linear regression analysis revealed that overall adherence to prescribed treatment and duration since onset of diabetes were significantly associated with glycemic control.We found that with improving overall adherence to OHAs, the HbA1c levels tend to decrease. We also noticed that as time since diagnosis of the diabetes increased the HbA1c values tend to rise. This is possible as diabetes is a condition in which the functioning of the beta cells of the pancreas progressively deteriorates with time (55).

7. LIMITATIONS.

1. The study used the technique of pill counting to measure compliance to treatment. Although the method is valid, it had its own limitations in terms of inadequate documentation in the patient retained chronic disease cards, lost or misplaced drugs and drug sharing between family members.

2. Physical activity was measured using the Global Physical Activity questionnaire. There are possibilities of random misclassification depending on the comprehension levels of the subjects and their responses.

3. As each person's body mass index was not estimated the impact of this important variable on the glycemic control could not be assessed.

8. SUMMARY AND CONCLUSIONS

1.   Compliance rate to drug therapy among patients with Diabetes mellitus in Kaniyambadi block , being treated in the mobile clinics is as follows:

*   Compliance to metformin: 49 out of the 97 prescribed were compliant (50.5%)

*   Compliance to glibenclamide: 29 out of the 64 prescribed glibenclamide were compliant (45.3%)

*   Percentage of people who had compliance rates of more than 100% (those who were taking more tablets than advised) was 24%

2.   Level of physical activity among the patients with diabetes:

*   High level of physical activity = 1%

*   Moderate level of physical activity = 60%

*   Low level of physical activity = 39%

3.   The average nutritional intake among this population was 1614.83 Kcals (95% CI = 1494.572 -1735.1 Kcal)

4.   Percentage of people with well controlled sugars(HbA1c $<$7%) was 53%, (95% CI = 43.2% to 62.78%)

5.   Percentage of people with a HbA1c of less than 6.5% was 37%

6.   No correlation was found between HbA1c and nutritional intake (r= -0.023)

7.   No significant association was found between sedentary lifestyle and uncontrolled sugars.

8.   Those who have missed a clinic and have irregular attendance to the mobile clinic are at a higher risk of having poorly controlled sugars.

9.   Through linear regression analysis it was found that HbA1c significantly reduced with better adherence.

10.   The risk of poorly controlled sugars increases with time since diagnosis.

9. RECOMMENDATIONS

1.   The compliance rate to medication and glycemic control among the patients visiting the doctor-run clinic is comparable with studies done at hospital settings. However better follow up of those who miss clinics may be needed as they are at a higher risk of having uncontrolled sugars.

2.   The mobile clinic is visited by fewer men and this needs to be looked into given that the rate of increase of diabetes among the male population in rural areas is higher than that of women.

3.   Involving the patients in setting targets for glycemic control may help in achieving better glycemic control.

4.   Thirty nine percent of the population is not exercising sufficiently. More emphasis needs to be given on increasing the levels of physical activity in the ongoing diabetes management program.

5.   There are many advantages of a doctor-run clinic but one major advantage is that care is subsidized based on the socioeconomic status of each individual. This is a clear message that chronic illnesses are a financial burden and people require financial assistance in the treatment of these illnesses.

6.   Diet advice needs to be given clearly to patients with diabetes.

10. BIBLIOGRAPHY

1. Sattley M. The history of diabetes. Diabetes Health [Internet]. 1996 Nov [Cited 2012 Aug26]; Available from: http://www.diabeteshealth.com/read/2008/12/17/715/the-history-of-diabetes/

2. Mohan V, Deepa M, Deepa R, Shanthirani CS, Farooq S, Ganesan A, et al. Secular trends in the prevalence of diabetes and impaired glucose tolerance in urban South India--the Chennai Urban Rural Epidemiology Study (CURES-17). Diabetologia. 2006 June;49(6):1175–8.

3. Orozco LJ, Buchleitner AM, Gimenez-Perez G, Roqué i Figuls M, Richter B, Mauricio D. Exercise or exercise and diet for preventing type 2 diabetes mellitus. Cochrane Database of Systematic Reviews [Internet]. John Wiley & Sons, Ltd; 1996 [cited 2012 Dec 5]. Available from: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003054.pub3/abstract

4. Vermeire EI, Wens J, Van Royen P, Biot Y, Hearnshaw H, Lindenmeyer A. Interventions for improving adherence to treatment recommendations in people with type 2 diabetes mellitus. Cochrane Database of Systematic Reviews [Internet]. John Wiley & Sons, Ltd; 1996 [cited 2012 Dec 5]. Available from: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003638.pub2/abstract

5. Meetoo D, McGovern P, Safadi R. An epidemiological overview of diabetes across the world.Br J Nurs. 2007 Sep 13;16(16):1002–7.

6. Gersh BJ, Sliwa K, Mayosi BM, Yusuf S. Novel therapeutic concepts: the epidemic of cardiovascular disease in the developing world: global implications. European Heart Journal. 2010 March;31(6):642–8.

7. Report of a WHO consultation. Definition, Diagnosis and Classification of Diabetes mellitus and its Complications [Internet].WHO; 1999. [Cited 2012 August 28]. Available from: www.staff.ncl.ac.uk/philip.home/who_dmc.htm/

8. Sadikot.S.M From Ants to Anologues ..... A history of diabetes. [Internet].2006.[Cited 2012 August 28]. Available from: http://www.diabetesindia.com/diabetes/history_diabetes2.htm

9. nobelprize.org. the discovery of insulin. 2009 Feb.[Cited 2012 August 26] Available from: http://www.nobelprize.org/educational/medicine/insulin/discovery-insulin.html

10.   Younk LM, Mikeladze M, Tate D, Davis SN. Exercise-related hypoglycemia in diabetes mellitus. Expert Rev Endocrinolology Metabolism. 2011 Jan 1;6(1):93–108.

11. Rewers M. Challenges in Diagnosing Type 1 Diabetes in Different Populations. Diabetes Metabolism J. 2012 Apr;36(2):90–7.

12. Report of a WHO consultation. definition, diagnosis and classification of diabetes mellitus and its complication. 1999; [Cited 2012 August 27]. Available from: http://whqlibdoc.who.int/hq/1999/who_ncd_ncs_99.2.pdf

13. ICMR. ICMR guidelines for management of diabetes.India.2005.

14. Heilbronn LK, Noakes M, Clifton PM. Effect of energy restriction, weight loss, and diet composition on plasma lipids and glucose in patients with type 2 diabetes. Diabetes Care. 1999 Jun;22(6):889–95.

15. Castañeda-González LM, Bacardí Gascón M, Jiménez Cruz A. Effects of low carbohydrate diets on weight and glycemic control among type 2 diabetes individuals: a systemic review of RCT greater than 12 weeks. Nutr Hosp. 2011 Dec;26(6):1270–6.

16. Riccardi G, Rivellese AA. Effects of dietary fiber and carbohydrate on glucose and lipoprotein metabolism in diabetic patients.Diabetes Care. 1991 Dec;14(12):1115–25.

17. Haimoto H, Sasakabe T, Umegaki H, Wakai K. Reduction in urinary albumin excretion with a moderate low-carbohydrate diet in patients with type 2 diabetes: a 12-month intervention. Diabetes Metab Syndr Obes. 2012;5:283–91.

18. Moore H, Summerbell C, Hooper L, Cruickshank K, Vyas A, Johnstone P, et al. Dietary advice for treatment of type 2 diabetes mellitus in adults. Cochrane Database Syst Rev. 2004;(3):CD004097.

19. Barakat A, Williams KM, Prevost AT, Kinmonth A-L, Wareham NJ, Griffin SJ, et al. Changes in physical activity and modelled cardiovascular risk following diagnosis of diabetes: 1-year results from the ADDITION-Cambridge trial cohort. Diabet.Med. [Internet]. 2012 Aug 22 [cited 2012 Aug 29]; Available from: http://www.ncbi.nlm.nih.gov/pubmed/22913463

20. Mohan V, Sandeep S, Deepa V, Shah B and Varghese C. Epidemiology of type 2 diabetes: Indian scenario. Indian J Med Res. 2007 Mar;125:217–230.

21. Vessby B, Karlström B, Boberg M, Lithell H, Gustafsson IB, Berne C. Diet therapy for poorly controlled type 2 (non-insulin-dependent) diabetes mellitus. Acta Paediatr Scand Suppl. 1985;320:44–49.

22. Krentz AJ, Bailey CJ. Oral antidiabetic agents: current role in type 2 diabetes mellitus. Drugs. 2005;65(3):385–411.

23. Saenz A, Fernandez-Esteban I, Mataix A, Ausejo Segura M, Roqué i Figuls M, Moher D. Metformin monotherapy for type 2 diabetes mellitus. Cochrane Database of Systematic Reviews [Internet]. John Wiley & Sons, Ltd; 1996 [cited 2012 Dec 5]. Available from: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD002966.pub3/abstract

24. Ali S, Fonseca V. Overview of metformin : special focus on metformin extended release. Expert Opin Pharmacother. 2012 Aug;13(12):1797–805.

25. Bron M, Marynchenko M, Yang H, Yu AP, Wu EQ. Hypoglycemia, treatment discontinuation, and costs in patients with type 2 diabetes mellitus on oral antidiabetic drugs. Postgrad Med. 2012 Jan;124(1):124–32.

26. Richter B, Bandeira-Echtler E, Bergerhoff K, Clar C, Ebrahim SH. Pioglitazone for type 2 diabetes mellitus. Cochrane Database of Systematic Reviews [Internet]. John Wiley & Sons, Ltd; 1996 [cited 2012 Dec 5]. Available from: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006060.pub2/abstract

27. Little RR, Sacks DB. HbA1c: how do we measure it and what does it mean? Current Opinion in Endocrinology, Diabetes and Obesity. 2009 Apr;16(2):113–8.

28. Manley S. Haemoglobin A1c--a marker for complications of type 2 diabetes: the experience from the UK Prospective Diabetes Study (UKPDS). Clin. Chem. Lab. Med. 2003 Sep;41(9):1182–90.

29. The Diabetes Control and Complications Trial Research Group. The Effect of Intensive Treatment of Diabetes on the Development and Progression of Long-Term Complications in Insulin-Dependent Diabetes Mellitus. N Engl J Med 1993; 329:977-986.

30. Rueda AM, Ormond M, Gore M, Matloobi M, Giordano TP, Musher DM. Hyperglycemia in diabetics and non-diabetics: effect on the risk for and severity of pneumococcal pneumonia. J. Infect. 2010 Feb;60(2):99–105.

31. Steenkamp DW, Alexanian SM, McDonnell ME. Adult Hyperglycemic Crisis: A Review and Perspective. Current Diabetes Reports [Internet]. 2012 Nov 1 [cited 2012 Dec 17]; Available from: http://rd.springer.com/article/10.1007%2Fs11892-012-0342-z

32. Foia L, Toma V, Ungureanu D, Aanei C, Costuleanu M. Relationship diabetes mellitus-periodontal disease: etiology and risk factors. Rev Med Chir Soc Med Nat Iasi. 2007 Sep;111(3):748–53.

33. Ban CR, Twigg SM. Fibrosis in diabetes complications: Pathogenic mechanisms and circulating and urinary markers. Vasc Health Risk Manag. 2008 Jun;4(3):575–96.

34. Noordzij MJ, Mulder DJ, Oomen PHN, Brouwer T, Jager J, Castro Cabezas M, et al. Skin autofluorescence and risk of micro- and macrovascular complications in patients with Type 2 diabetes mellitus-a multi-centre study. Diabet. Med. 2012 Dec;29(12):1556–61.

35. Autofluorescence [Internet]. Wikipedia, the free encyclopedia. January 2012 [Updated 2012 Oct 1;cited 2012 Dec 16]. Available from: http://en.wikipedia.org/w/index.php?title=Autofluorescence&oldid=515544252

36. Shaw JE, Sicree RA, Zimmet PZ. Global estimates of the prevalence of diabetes for 2010 and 2030 .Diabetes Res Clin. Pract. 2010 Jan; 87(1):4-14

37. Misra P, Upadhyay RP, Misra A, Anand K. A review of the epidemiology of diabetes in rural India.Diabetes Res. Clin.Pract. 2011 Jun;92(3):303–11.

38. Jin J, Sklar GE, Min Sen Oh V, Chuen Li S. Factors affecting therapeutic compliance: A review from the patient's perspective. Ther Clin Risk Manag. 2008 Feb;4(1):269–86.

39. Walker RJ, Smalls BL, Hernandez-Tejada MA, Campbell JA, Davis KS, Egede LE. Effect of diabetes fatalism on medication adherence and self-care behaviors in adults with diabetes. Gen Hosp Psychiatry [Internet]. 2012 Aug 13 [cited 2012 Aug 29]; Available from: http://www.ncbi.nlm.nih.gov/pubmed/22898447

40. Khan AR, Al-Abdul Lateef ZN, Al Aithan MA, Bu-Khamseen MA, Ibrahim IA, Khan SA. Factors contributing to non-compliance among diabetics attending primary health centers in the Al Hasa district of Saudi Arabia. J Family Community Med. 2012 Jan;19(1):26–32.

41. De León AC, Rodríguez JC del C, Coello SD, Pérez MDCR, Díaz BB, Alamo CB, et al. Lifestyle and treatment adherence of type 2 diabetes mellitus people in the Canary Islands. Rev. Esp. Salud Publica. 2009 Aug;83(4):567–75.

42. Lahiri SK, Haldar D, Chowdhury SP, Sarkar GN, Bhadury S, Datta UK. Junctures to the therapeutic goal of diabetes mellitus: Experience in a tertiary care hospital of Kolkata. J Midlife Health. 2011;2(1):31–6.

43. Al-Maskari F, El-Sadig M, Nagelkerke N. Assessment of the direct medical costs of diabetes mellitus and its complications in the United Arab Emirates. BMC Public Health. 2010 Nov 8;10:679.

44. Lafata JE, Dobie E, Morris H, Heisler M, Werner R, Divine G, et al. Collaborative Goal Setting and HbA1c Control Among Patients With Diabetes. Clin Med Res. 2012 Aug;10(3):160.

45. Yan XS, Bloom F, Stewart W, Pitcavage J. Reduced Risk of Incident Microvascular and Macrovascular Events Under Diabetes Bundle Management. Clin Med Res. 2012 Aug;10(3):160–1.

46. National Institute of Health and Family Welfare. National Diabetes Control Programme .India. 2009. Available from: http://www.nihfw.org/NDC/DocumentationServices/NationalHealthProgramme/NATIONALDIABETESCONTROLPROGRAMME.html

47. H.T Pandve, P.S Chawla, K.Fernandez,S.A.Singru. Recent developments in Diabetes Control and Prevention in India.[Internet]. 2010 Oct 1 [Cited 2012 August 28] . Available from: http://www.rssdi.in/diabetesbulletin/2010/JULY/IntJDiabDevCtries303171-4643849_011723.pdf

48. Bull FC, Maslin TS, Armstrong T. Global physical activity questionnaire (GPAQ): nine country reliability and validity study. J Phys Act Health. 2009 Nov;6(6):790–804.

49. Van den Boogaard J, Lyimo RA, Boeree MJ, Kibiki GS, Aarnoutse RE. Electronic monitoring of treatment adherence and validation of alternative adherence measures in tuberculosis patients: a pilot study. Bull. World Health Organ. 2011 Sep 1;89(9):632–9.

50. Farmer KC. Methods for measuring and monitoring medication regimen adherence in clinical trials and clinical practice. Clin Ther. 1999 Jun;21(6):1074–1090; discussion 1073.

51.Choo PW, Rand CS, Inui TS, Lee ML, Cain E, Cordeiro-Breault M, et al. Validation of patient reports, automated pharmacy records, and pill counts with electronic monitoring of adherence to antihypertensive therapy.Med Care. 1999 Sep;37(9):846–57.

52. Buchanan TS, Berg CJ, Cox LS, Nazir N, Benowitz NL, Yu L, et al. Adherence to Varenicline among African American Smokers: An Exploratory Analysis Comparing Plasma Concentration, Pill Count, and Self-Report. Nicotine Tob Res. 2012 Sep;14(9):1083-91.

53. Venkataraman K, Kannan AT, Mohan V. Challenges in diabetes management with particular reference to India. Int J Diabetes Dev Ctries. 2009;29(3):103–9.

54. Nield L, Moore H, Hooper L, Cruickshank K, Vyas A, Whittaker V, et al. Dietary advice for treatment of type 2 diabetes mellitus in adults. Cochrane Database of Systematic Reviews [Internet]. John Wiley & Sons, Ltd; 1996 [cited 2012 Dec 5]. Available from: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004097.pub4/abstract

55. Cnop M, Welsh N, Jonas J-C, Jörns A, Lenzen S, Eizirik DL. Mechanisms of pancreatic beta-cell death in type 1 and type 2 diabetes: many differences, few similarities.Diabetes. 2005 Dec;54 Suppl 2:97–107.

11. ANNEXURE

Index of annexure:

Annexure 1: Information and consent form- Tamil version

Annexure 2: Information and consent sheet- English version

Annexure 3: Modified Kuppusamy scale for 2012

Annexure 4: Protocol for 24 hour diet recall

Annexure 5: Dietary guidelines for Indians, National Institute of Nutrition, Hyderabad.

Annexure 6: Global physical Activity questionnaire.

Annexure 1 :

Information and consent form :Tamil version

தகவல் படிவம்

நான் மருத்துவராகபணிபுரியும் சாட் மருத்துவமனையில் நீங்கள் சர்க்கரை

நோய்க்காகசிகிச்சைளடுத்துக்கொண்டிருக்கிறீர்கள்என்பதைஅறிந்துள்ளே

ன்.

தங்களைபோன்றநோயாளிகள் எந்தஅளவிற்குசிகிச்சைமுறையோடு

ஒத்துழைத்துஒருங்கிணைந்துபோகிறார்கள் என்பதுதொடர்பானஓர்

ஆய்வைச்செய்யஉள்ளேன். நான் உங்களிடம் உங்களுடையஉணவுப்

பழக்கங்கள், உடல்வேலைபஞு, மருந்துஉட்கொள்ளுதல்

தொடர்பாகசிலகேள்விகளைகேட்பேன்.

அதோடுஒருசிலநோயாளிகள் எவ்வளவு அளவு உணவு

உட்கொள்ளுகிறார்கள்என்பதுபற்றிதெரிந்துகொள்ளவும்

அனுமதிதேவைப்படுகிறது. ஆய்வில்பங்குபெறும்

எல்லாமக்களிடமிருந்தும் சிறிதளவு இரத்தம் எடுத்து இரத்தத்தில்

சர்க்கரையின் அளவு கடந்தமூன்றுமாதங்களில் எவ்வளவு இருந்ததுஎன்று

கண்டறியவும் இரத்தஹீமோகுளோபினில் சர்க்கரைமூலக்கூறுஉள்ளதான

கண்டறியவும் தேவைப்படுகிறது. இந்தஆய்வில் நீங்கள் பங்குபெற்றால்

எனக்குமிகவும் உதவியாக இருக்கும். நீங்கள் இந்தஆய்வில் பங்கு

பெறாவிட்டாலும் சாட் மருத்துவமனையில் கிடைக்கும் மருத்துவசேவைகளைதொடர்ந்துபயன்படுத்தலாம். நீங்கள் இந்தஆய்வில் பங்குபெற்றால் இரத்தப்பரிசோதனைமுடிவு உங்களுக்குதெரியப்படுத்தப்படும்.

ஒப்புதல் படிவம்

நான் (பெயர்) (கணவர் பெயர்)

இந்தஆய்வைப்பற்றியமுழுமையானதகவல்களைஅறிந்துக் கொண்டேன். மற்றும் இந்தஆய்வில் பங்குகொள்ளஎன்னுடைய முழு சம்மத்தைத் தெரிவித்துக் கொள்கிறேன்.

ஒப்புதல் அளிப்பவரின் பெயர்

கையெழுத்து / இடதுபெருவிரல் ரேகை

ஆய்வாளர் கையொப்பம்

தேதி

107

கேள்விகள்

சர்க்கரைநோய் வகையிஉள்ளவர்கள் உட்கொள்ளும் மாத்திரைகள் தொடர்பானஆய்வு

1. பெயர்

2. வயது

3. நோயாளியின் மருத்துவமனை / ஆய்வு எண்

4. தொழில்:

5. கல்விநிலை:

6. Modified Kuppusamy Scale :

	Highest in Family	Score
தொழில்		
கல்விநிலை		
மாதகுடும்பவருமானம்		

7. சர்க்கரைநோய் கண்டுபிடித்தபின் ஆகும் வருடங்கள்

8. சர்க்கரைநோய் தவிரவேறுஏதேனும் சுகவீனம் இருந்தால் அவற்றைவரிசைப்படுத்துக:

9. மது அருந்தும் பழக்கம் உள்ளவர்: **ஆம் /இல்லை**

10. ஆம் என்றால், அளவு மற்றும் எவ்வளவு நாட்களுக்குஒருமுறைகுடிப்பீர்கள்?

11. புகையிலைபழக்கம் உள்ளவர்: **ஆம் /இல்லை**

12. ஆம் என்றால், அளவுமற்றும் எத்தனைமுறைஉபயோகிப்பீர்கள்

12. ஒருநாளைக்குஎத்தனைமாத்திரைசாப்பிடுகிறீர்கள்?

14. ஒருமாதத்திற்குமாத்திரைக்காகும் செலவு எவ்வளவு?

15. Current Prescription   Cost of Prescription

Drug	Dose	Frequency
Metformin		
Daonil		
Pioglitazone		

16. சர்க்கரைநோய் எதிர்ப்பு மாத்திரைபற்றியஅறிவைதெரிந்து

கொள்வதற்கானகேள்விகள்

a). உங்களுடையமருத்துவரால் உங்களுக்குபரிந்துரைக்கப்பட்ட

மாத்திரையின் பெயர் என்ன?

மாத்திரை 1 — கிளிபென்கிளமைடு

மாத்திரை 2 — மெட்பார்மின்

மாத்திரை 3 — பையோகிளிட்டசோன்

b).ஒவ்வொருமுறையும்எத்தனைமாத்திரைஉட்கொள்ளவேண்டும்

மாத்திரை அ — கிளிபென்கிளமைடு

- ஒவ்வொருமுறையும் ஒருமாத்திரை

- ஒவ்வொருமுறையும் 2 மாத்திரை
- ஒவ்வொருமுறையும் 1 1/2   மாத்திரை

மாத்திரை ஆ — மெட்பார்மின

- ஒவ்வொருமுறையும் ஒருமாத்திரை

- ஒவ்வொருமுறையும் 1 1/2   மாத்திரை

- ஒவ்வொருமுறையும் 2 மாத்திரை

மாத்திரை இ — பையோகிளிட்டசோன

- ஒவ்வொருமுறையும் ஒருமாத்திரை

- ஒவ்வொருமுறையும் 2 மாத்திரை

- ஒவ்வொருமுறையும 3 மாத்திரை

C. ஒருநாளைக்குளத்தனைமுறைநீங்கள் மாத்திரைஉட்கொள்ள

வேண்டும்

மாத்திரை அ — கிளிபென்கிளமைடு

- ஒருநாளிலஒருமுறை

- ஒருநாளில் இரண்டுமுறை

- ஒருநாளில் மூன்றுமுறை

மாத்திரை ஆ — மெட்பார்மின

- ஒருநாளிலஒருமுறை

- ஒருநாளில் இரண்டுமுறை

-   ஒருநாளில் மூன்றுமுறை

1 7 . Date of last visit

18. மாத்திரைஎண்ணிக்கை

Drug	Observed	Expected
Metformin		
Daonil		
Pioglitazone		

நீங்கள் சாட் மருத்துவமனையிலிருந்து வாங்கிய மாத்திரைகளைதவிர்த்துவேறுயாரிடமிருந்தாவதுமாத்திரைகளை பகிர்ந்துகொள்கிறீர்களா? ஆம் என்றால், எத்தனை?

20. உங்களுக்குஏதேனும் பின்விளைவு / பக்கவிளைவுஏற்பட்டுள்ளதா? **ஆம் / இல்லை**

21.ஆம் என்றால் நீங்கள் அனுபவித்த பக்க விளைவுகளைப்பற்றி கூறுங்கள்

22. 24 மணிநேரம் உண்ணஉணவைப்பற்றி கூறுங்கள்

Meals	Food	Quantity	Calorie
Breakfast			
Lunch			
Dinner			
snacks			

23. உடல் வேலை

1. உங்களுடையவேலைமிகவும் கடினமானதும், வேலைபளு

அதிகமானதானவும் உங்களுடைய இருதயதுடிப்பும் சுவாசமும்

அதிகமாக்கும்படிஉள்ளதா?

(எடுத்துக்காட்டாகஅதிகமானஎடையுள்ளபொருளைத் தூக்குதல்,

தோண்டுதல், வீடுகட்டும் வேலை) இந்தஅறிகுறிதொடர்ந்து 1 0 நிமிடங்களுக்காவதுஉள்ளதா?   ஆம் / இல்லை

2. பொதுவாகஒருவாரத்தில் எத்தனைநாட்கள் மேற்கூறியகடினமானவேலைகளைசெய்வீர்கள்? (எண்ணிக்கை 1,2,3,4,5,6,7நாட்கள்)

3. ஒருநாளில் மிகவும் கடினமானவேலையைஎவ்வளவு நேரம் செய்வீர்கள்?

4. நீங்கள் சாதாரணமாகவேலைசெய்யும்போது உங்களுக்குஏற்படுகின்றசுவாசத்தில் அல்லது இதயதுடிப்பில் ஏதேனும் மாற்றம் ஏற்படுகின்றதா? (உம. குறைந்தஎடையுள்ளபொருட்களை தூக்கும்போதுதொடர்ச்சியாக 1 0 நிமிடங்களுக்குமூச்சுவாங்குதல்)

ஆம் /இல்லை

5. ஒருவாரத்தில் பொதுவாகசராசரியானவேலைப் பளுஉள்ளவேலையைஎத்தனைநாட்கள் செய்வீர்கள்?   (நாட்கள்)

6. ஒருநாளைக்குள்தனைமணிநேரம் நீங்கள்
கடினமானவேலைசெய்கீறீர்கள்? (நேரம் நிமிடங்களில்)

7. நீங்கள் பொதுவாகஒரு இடத்திற்குசென்றுதிரும்பகுறைந்தது
10நிமிடத்திற்காவதுசைக்கிள் ஓட்டுவீர்களா?
அல்லதுநடப்பீர்களா? (ஆம் / இல்லை)

8. ஆம் என்றால், ஒருவாரத்தில் பொதுவாகஅத்தனைநாட்கள்
குறைந்ததுபத்துநிமிடங்கள் நடத்தல் (அல்லது) சைக்கிள்
ஓட்டுவீர்கள்? (நாட்கள்)

9. எங்காவது செல்வதற்காக பொதுவாகஒருநாளைக்கு
எத்தனைமுறைநடந்து (அல்லது) சைக்கிள் ஓட்டிசெல்வீர்கள்?
(மணிநிமிடங்கள்)

10. நீங்கள் சுவாசம் மற்றும் இருதயத்துடிப்பைஅதிகப்படுத்தும்
மிகவும் கடினமானவிளையாட்டு, உடல்
கட்டுக்கோப்புக்கானசெயல்கள்
அல்லதுபொழுதுபோக்கானசெயல்கள்
(எடுத்துக்காட்டாகஓடுதல், கால்பந்துவிளையாடுதல்)
குறைந்தது 10 நிமிடங்களுக்குசெய்வீர்களா
(ஆம் / இல்லை)

11. ஒருவாரத்தில் எத்தனைநாட்கள் கடினமானவிளையாட்டு, உடல்

கட்டுக்கோப்புக்கானபயிற்சிஅல்லதுபொழுதுபோக்குக்கானசெயல்களில் ஈடுபடுவீர்கள்

(நாட்கள்)

12. ஒருநாளில் எத்தனைமணிநேரம் கடினமானவிளையாட்டு, உடல்

கட்டுக்கோப்புக்கானபயிற்சிஅல்லதுபொழுதுபோக்குக்கானசெயல்களில் ஈடுபடுவீர்கள்

(மணிநிமிடங்கள்)

13. நீங்கள் சராசரியாகவேலைபளுவுள்ளவிளையாட்டு

உடற்கட்டுக்கோப்புக்கான செயல்

அல்லதுபொழுதுபோக்கானசெயல்கள் குறைந்தது 10

நிமிடங்களாவதுசெய்யும்போது இருதயத்துடிப்பும் சுவாசமும்

அதிகமாகுமா? (எடுத்துகாட்டாகவேகமாகநடத்தல், சைக்கிள்

ஓட்டுதல், நீந்துதல், கைபந்துவிளையாடுதல்)

(ஆம் / இல்லை)

14. சராசரியானவேலைபளுவுள்ளவிளையாட்டு,

உடற்கட்டுக்கோப்புக்கான செயல்

அல்லதுபொழுதுபோக்கானசெயல்கள் ஒருவாரத்தில்
எத்தனைநாட்கள் செய்வீர்கள்? (நாட்கள்)

15. சராசரியானவேலைபளுவுள்ளவிளையாட்டு,
உடற்கட்டுக்கோப்புக்கான செயல்
அல்லதுபொழுதுபோக்கானசெயல்கள் ஒருநாளில் எவ்வளவு
நேரம் செய்வீர்கள்? (மணி/நிமிடங்கள்)

16. பொதுவாகஒருநாளில் எவ்வளவு நேரம் உட்காருவதற்கும்
சாய்ந்து இருந்துஓய்வு எடுக்கவும் செலவு செய்வீர்கள் (
மணி/நிமிடங்கள்)

Information and consent form with questionnaire: English version

Informed consent

Study on rate of compliance among patients on treatment for diabetes in CHAD mobile clinic.

I understand that you have been taking treatment for diabetes mellitus from CHAD hospital, where I work as a doctor. I am conducting a study to see how patients like you are coping with the treatment.

I will be asking a few questions related to your dietary intake, routine physical activity and drug compliance. I will need a few patients to permit me to weigh the amount of food they eat regularly. I will be collecting blood from all participants to measure HbA1c, a measure of their sugar control over the last 3 months.

I will be grateful if you are willing to participate in this study. If you participate, you will not be paid any money or medicines as compensation and you will have to sign on this document. If you are not willing to participate in this study you can still continue to use the services that CHAD hospital provides. If you choose to participate in this study your results will be maintained confidential and the results of your blood tests will be revealed only to you.

I, (name)…………………………., (s/o or w/o)………………………….. have understood the information on this study and give my consent to participate in this study.

Name of participant:

Study number   :

Signature or thumb impression: date:

Signature of investigator: date:

Signature of witness: date:

Questionnaire

Study on rate of compliance among men on treatment for diabetes in CHAD mobile clinic

1. Name   :
2. Age   :
3. Study number   :
4. Village number   :
5. No. of years since diagnosis of diabetes :
6. List of co-morbid conditions   :
7. Use of alcohol   : (y/n)
If yes, specify the amount used per week:
8.   Use of tobacco   : (y/n)
If yes, specify pack years:
9.   Number of pills per day (including all drugs) :
10. Actual Cost of the prescription:
11.   Money spent per month on drugs:
12. SES (Modified Kuppusamy score):

Education		
Occupation		
Monthly family income		

13. <u>knowledge of prescription:</u>

From the medical record of the diabetic patient, the family physician's prescription must be identified. Check (**√**) the corresponding box if the statement corresponds to the information written in the medical record of a diabetic patient.

14.   Medication prescribed A: Glibenclamide dosage:

                                 1 tablet at each intake

                                 2 tablets at each intake

15.   Glibenclamide dosage frequency:

                                 Medication once a day:

                                 Medication twice a day:

                                 Medication three times a day:

16.   Medication prescribed B: Metformin dosage:

                              1 tablet at each intake:

                              2 tablets at each intake:

17.   Metformin dosage frequency:

                              Medication once a day:

                              Medication twice a day:

                              Medication three times a day:

18.   Medication prescribed C : Pioglitazone dosage

                              1 tablet at each intake

                              2 tablets at each intake

                              3 tablets at each intake

19.   Pioglitazone dosage frequency:

                              Once a day

                              Twice a day

                              Three times a day

20.With the following three questions we wish to know how you take the medication prescribed by your family physician at the last medical visit. If the patient´s answer corresponds with the information listed in the last section check (**v**) the corresponding box of the statement, otherwise place an (**x**). If the medication is not prescribed, leave the box blank.

KQ. 1.   What is the name of the diabetes medication prescribed by your family physician?
Medication A: Glibenclamide*:   ☐
Medication B: Metformin:*   ☐
Medication C: Pioglitazone*   ☐

KQ. 2.   How many tablets a day do you have to consume at each intake?
Medication A: Glibenclamide:
    1 tablet at each intake: ☐
    2 tablets at each intake: ☐
Medication B: Metformin:
    1 tablet at each intake: ☐
    2 tablets at each intake: ☐
Medication C: Pioglitazone:
    1 tablet at each intake: ☐
    2 tablets at each intake: ☐
    3 tablets at each intake: ☐
KQ. 3.   How many times a day do you have to take your medication?
Medication A: Glibenclamide:
    Once a day: ☐
    Twice a day: ☐
    Three times a day: ☐
Medication B: Metformin:
    Once a day: ☐
    Twice a day: ☐
    Three times a day: ☐
Medication C: Pioglitazone:
    Once a day: ☐
    Twice a day: ☐
    Three times a day: ☐

21. Pill count:

Name of drug	Expected number	Observed
Metformin		
Glibenclamide		
Pioglitazone		

22. No. of pills acquired from other sources during the month:
23. List some of the reasons for non adherence:

Side effects   : (Y/N)
Cost of drugs   : (Y/N)
Frequent travelling   : (Y/N)
Forgetfulness   : (Y/N)
They are not needed   : (Y/N)
Any other reasons (specify):

24. 24 hour diet recall:

Total caloric intake:

Meal	Food items	Calories
Breakfast		
Lunch		
dinner		
snacks		

Physical activity: (WHO STEPS Questionnaire)

25.Does your work involve vigorous-intensity activity that causes large increases in breathing or heart rate like for at least 10 minutes continuously? (yes/no)

26. In a typical week, on how many days do you do vigorous-intensity activities as part of your work? (Number of days)

27 How much time do you spend doing vigorous-intensity activities at work on a typical day? (Hours : minutes)

 28.   Does your work involve moderate-intensity activity, that causes small increases in breathing or heart rate such as brisk walking for at least 10 minutes continuously?

29. In a typical week, on how many days do you do moderate-intensity activities as part of your work?

  Number of day's ____

30.   How much time do you spend doing moderate-intensity activities at work on a typical day?
    Hours: minutes (……..:……)

31. Do you walk or use a bicycle (*pedal cycle*) for at least 10 minutes continuously to get to and from places? (y/n)

32. In a typical week, on how many days do you walk or bicycle for at least 10 minutes continuously to get to places? _____(number of days)

33.   How much time do you spend walking or bicycling for travel on a typical day?
Hours : minutes _____: _____

34.Do you do any vigorous-intensity sports, fitness or recreational (*leisure*) activities that cause large increases in breathing or heart rate like [*running orfootball,*] for at least 10 minutes continuously: (yes/no)

35. In a typical week, on how many days do you do vigorous-intensity sports, fitness or recreational (*leisure*) activities::_____ no. of days

36.How much time do you spend doing vigorous-intensity

sports, fitness or recreational activities on a typical day? _____(hrs:mins)

37.   Do   you   do   any   moderate-intensity   sports,   fitness orrecreational(*leisure*) activities that causes a smallincrease in breathing or heart rate such as briskwalking,(*cycling, swimming, volleyball*)for at least 10
minutes continuously? : (yes/no)

38 In a typical week, on how many days do you do moderate-intensity sports, fitness or recreational(*leisure*) activities?

_____Number of days

39.How much time do you spend doing moderate-intensity sports, fitness or recreational (*leisure*) activities on a typical day?

_____(hrs: mins)

40.How much time do you usually spend sitting or reclining on a typical day?

Hours: minutes_____:_____

Equivalent activites:

Moderate intensity	Vigorous intensity
Walking briskly Bicycling (slower than 10 miles per hour) Water aerobics tennis doubles General gardening	Race walking, running, jogging, heavy gardening, hiking uphill Swimming, Tennis singles Bicycling faster than 10 miles per hour.

Annexure 3

Modified Kuppusamy scale for socioeconomic status (2012):

Education:

Professional/honours	7
Graduation/ post graduation	6
Inter/post high school diploma	5
High school certificate	4
Middle school	3
Primary school	2
illiterate	1

Occupation:

Profession	10
Semi profession	6
Clerical/ shop owner/farmer	5
Skilled labour	4
Semi skilledlabour	3
Unskilled labour	2
unemployed	1

Family income per month in rupees:

>= 30,375	12
15,188 - 30,374	10
11,362 - 15,187	6
7,594 – 11,361	4
4,556 – 7,593	3
1,521- 4,555	2
<=1520	1

SCORE	CLASSIFICATION	CLASS
26-29	I	
16-25	II	
11-15	III	
5-10	IV	
<5	V	

Annexure 4 :

Protocol followed for the 24 hour diet recall:

Adapted from Texas A&M University and Iowa State University, 8/06 by: Candace Gabel, MS, RD, LD and Ellen Schuster MS, RD.

1.   Explain to the participant that you need to know only what she (he) actually ate. She (he) should not feel embarrassed about any food, as there are no "good" or "bad" foods. No one eats just the right foods all the time.

2.   Do not express in words or facial expressions either approval or disapproval of foods mentioned by the participant.

3.   Do not ask questions that would lead the participant to feel she (he) "should" have had a certain item and, thus say that they did.

4.   Use your Food Recall Kit to determine the amounts of foods consumed.

5.   Start with the most recent meal or snack that the participant consumed. Work backwards to cover all foods and beverage consumed in the last 24 hours or in a "typical day". Weekends and holidays are not typical days and recalls from these days may provide an inaccurate view of the participant's diet.

6. **Quick List**:

Record the list of foods as the homemaker remembers them; portion sizes and preparation methods will be recorded in the next step. This list of foods is termed the quick list. To obtain this list of foods from the participant use the following types of probes to find **what foods** were eaten:

A.   The first type of probing is related to **time**.

Examples:

"At what time was this? Did you eat or drink anything before or after that?"

"What did you have at that time?"

"At what time did you go to bed?"

B. The second type of probe is related to the participant's **activities.**

Examples:

"What did you do this morning?"

"While you were working around the house, did you take a break to have something to eat or drink?"

"Did you watch TV last night? When you watched TV, did you eat anything?"

"Did you have anything to drink with this?"

C.   The third type of probe tries to get more complete **information about foods already reported.**

Examples:

"Do you remember anything else that you ate or drank with this food?"

"What else did you have at this meal?"

"Was the (bread, vegetable) eaten plain or did you put something on it?

"Did you have anything in your coffee?"

"Did you have a second helping?"

7. **Detailed Description**:

After you have recorded the participant's quick list, you can then complete the detailed description of foods consumed. This will include recording preparation method, brand name, portion size, and the time the food or beverage was consumed. To get more information on the amounts and the type of foods eaten use the following techniques:

A.   Determine if all of the food was eaten or if some food was left on the plate.

B.   Encourage the participant to describe foods as clearly as possible. The interviewer may have to restate questions to get more information.

C.   Describe combination dishes carefully. Mixtures such as sandwiches, soups, stew, pizza, casseroles, etc. can be prepared in many ways.

D.   Ask to see packages, if available, on prepackaged foods, and record brand name and other pertinent information.

8. Review **-** Once the 24 hour food recall is complete read the list back to the participant. Ask the participant if the recall is correct or if they forgot to mention any food was consumed

9. Thank the participant for their cooperation. Do not comment on the recall atthis time, unless the participant asks a specific question.

10. Tell the participant that they will be getting a printout of their food recalland a summary of how their food intake meets USDA's MyPyramid recommendations.

11. Wait and address deficiencies, excesses, etc. when the diet summary is

reviewed and when lessons are taught that deal with that area of the diet.

12. Give each participant a copy of "What Should I Eat."

Annexure 5:

Dietary guidelines for Indians, National Institute of Nutrition, Hyderabad

Approximate caloric value of fruits and nuts

	Portion	Calories
Nuts		
Almonds	10 Nos.	85
Cashewnuts	10 Nos.	95
Coconut (fresh)	100 g	444
Coconut (dry)	100 g	662
Peanuts	50 Nos.	90
Fresh fruits		
Apple	1 medium	65
Banana	1 medium	90
Grapes	30 Nos.	70
Guava	1 medium	50
Jackfruit	4 pieces	90
Mango	1 medium	180
Mosambi/orange	1 medium	40
Papaya	1 piece	80
Pineapple	1 piece	50
Sapota	1 medium	80
Custard apple	1 medium	130
Watermelon/muskmelon	1 slice	15
Salads		
Beetroot	1 medium	30
Carrot	1 medium	70
Cucumber	1 medium	12
Onion	1 medium	25
Radish	1 medium	10
Tomato	1 medium	10

Low calorie vegetables and fruits (20 kcal)

Name of the vegetables	Kcal
GLV	
Amaranth (stem)	19
Ambat chukka	15
Celery stalk	18
Ipomoea stem	19
Spinach stalk	20
Roots and tubers	
Radish table	16
Radish white	17
Other vegetables	
Ash gourd	10
Bottle gourd	12
Cluster beans	16
Colocasia stem	18
Cucumber	13
Ghosala	18
Kovai	18
Parwal	20
Ridge guard	17
Snake guard	18
Vegetable marrow	17
Fruits	
Bilimbi	19
Jamb safed	19
Musk melon	17
Water melon	16
Orange juice	9
Tomato ripe	20

Source: Nutritive Value of Indian Foods, 2006

Vegetables and Fruits with High calorie value ($\geq$ 100kcal)

Food Stuff	Kcal/100g
Leafy vegetables	
Chekkurmanis	103
Colocasia leaves (dried)	277
Curry leaves	108
Fetid cassia (dried) (Chakunda)	292
Rape leaves (dried)	297
Tamarind leaves	115
Roots & Tubers	
Arrow root flour	334
Parsnip	101
Sweet potato	120
Tapioca	157
Yam ordinary	111
Yam wild	110
Other vegetables	
Beans, scarlet runner	158
Jack fruit, seeds	133
Karonda (dry)	364
Lotus stem (dry)	234
Sundakai (dry)	269
Water chestnut (fresh)	115
Water chestnut (dry)	330
Fruits	
Apricot (dry)	306
Avacado pear	215
Banana	116
Bael fruit	116
Currants, red	316
Dates (dried)	317
Dates fresh	144
Mahua (ripe)	111
Raisins	308
Seetaphal	104
Wood apple	134

Source: Nutritive Value of Indian Foods, 2006

Approximate Calorific Value of Some Cooked Preparations

Preparation		Quantity for one serving		Calories
				(Kcal)
1.	Cereal			
	Rice	1 cup		170
	Phulka	1	No.	80
	Paratha	1	No.	150
	Puri	1	No.	80
	Bread	2 slices		170
	Poha	1 cup		270
	Upma	1 cup		270
	Idli	2	Nos.	150
	Dosa	1 No.		125
	Kichidi	1 cup		200
	Wheat porridge	1 cup		220
	Semolina porridge	1 cup		220
	Cereal flakes with milk (corn/wheat/rice)	1 cup		220
2.	Pulse			
	Plain dhal	½ cup		100
	Sambar	1 cup		110
3.	Vegetable			
	With gravy	1 cup		170
	Dry	1 cup		150
4.	Non-Vegetarian			
	Boiled egg	1	No.	90
	Ommelette	1	No.	160
	Fried egg	1	No.	160
	Mutton curry	¾ cup		260
	Chicken curry	¾ cup		240
	Fish fried	2 big pieces		190
	Fish cutlet	2	Nos.	190
	Prawn curry	¾ cup		220
	Keemakofta curry	¾ cup		240
		(6 small koftas)		

Approximate Calorific Value of Some Cooked Preparations

Preparation	Quantity for one serving		Calories (Kcal)
5. Savoury snacks			
Bajji or pakora	8	Nos.	280
Besankapura	1	No.	220
Chat (Dahi-pakori)	5 pieces		220
Cheese balls	2	Nos.	250
Dahivada	2	Nos.	180
Vada	2	Nos.	140
Masala vada	2	Nos.	150
Masala dosa	1	No.	200
Pea-kachori	2	Nos.	380
Potato bonda	2	Nos.	200
Sago vada	2	Nos.	210
Samosa	1 No.		200
Sandwiches (butter - 2tbsp)	2	Nos.	200
Vegetable puff	1	No.	200
Pizza (Cheese and tomato)	1 slice		200
6. Chutneys			
Coconut/groundnuts/til	2 tbsp		120
Tomato	1 tbsp		10
Tamarind (with jaggery)	1 tbsp		60
7. Sweets and Desserts			
Besanbarfi	2 small pieces		400
Chikki	2 pieces		290
Fruit cake	1 piece		270
Rice puttu	½ cup		280
Sandesh	2	Nos.	140
Double kameetha	½ cup		280
Halwa (kesari)	½ cup		320
Jelly/Jam	1 tbsp		20
Custard (caramel)	½ cup		160
Srikhand	½ cup		380
Milk chocolate	25 g		140
Ice-cream	½ cup		200

Preparation		Quantity for one serving	Calories(Kcal)
8. Beverages			
Tea	(2 tsp sugar +	1 cup	75
	50 ml toned milk)		
Coffee	(2 tsp sugar +	1 cup	110
	100 ml)		
Cow's milk	(2 tsp sugar)	1 cup	180
Buffalo's milk (2 tsp sugar)		1 cup	320
Lassi	(2 tsp sugar)	1 cup/glass (200 ml)	110
Squash		1 cup/glass	75
Syrups (Sharabats)		1 cup/glass	200
Cold drinks		1 bottle (200 ml)	150
Fresh lime juice		1 glass	60

Annexure 6:

Global Physical Activity questionnaire:

CORE: Physical Activity

Next I am going to ask you about the time you spend doing different types of physical activity in a typical week. Please answer these questions even if you do not consider yourself to be a physically active person.

Think first about the time you spend doing work. Think of work as the things that you have to do such as paid or unpaid work, study/training, household chores, harvesting food/crops, fishing or hunting for food, seeking employment. *[Insert other examples if needed].* In answering the following questions 'vigorous-intensity activities' are activities that require hard physical effort and cause large increases in breathing or heart rate, 'moderate-intensity activities' are activities that require moderate physical effort and cause small increases in breathing or heart rate.

Read this opening statement out loud. It should not be omitted. The respondent will have to think first about the time he/she spends doing work (paid or unpaid work, household chores, harvesting food, fishing or hunting for food, seeking employment [Insert other examples if needed]), then about the time he/she travels from place to place, and finally about the time spent in vigorous as well as moderate physical activity during leisure time.

Remind the respondent when he/she answers the following questions that 'vigorous-intensity activities' are activities that require hard physical effort and cause large increases in breathing or heart rate, 'moderate-intensity activities' are activities that require moderate physical effort and cause small increases in breathing or heart rate. Don't forget to use the showcard which will help the respondent when answering to the questions.

Question		Response	Code
52	**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?** *Activities are regarded as vigorous intensity if they cause a large increase in breathing and/or heart rate.* *[INSERT EXAMPLES] (USE SHOWCARD)*	**Yes** 1 **No** 2 *If No, go to P 4*	**P1**
53	**In a typical week, on how many days do you do vigorous-intensity activities as part of your work?** *"Typical week" means a week when a person is doing vigorous intensity activities and not an average over a period. Valid responses range from 1-7.*	**Number of days**	**P2**
54	**How much time do you spend doing vigorous-intensity activities at work on a typical day?** *Think of one day you can recall easily. Consider only those activities undertaken continuously for 10 minutes or more. Probe very high responses (over 4 hrs) to verify.*	**Hours : minutes** hrs mins	**P3 (a-b)**
55	**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?** *Activities are regarded as moderate intensity if they cause a small increase in breathing and/or heart rate.* *[INSERT EXAMPLES] (USE SHOWCARD)*	**Yes** 1 **No** 2 *If No, go to P 7*	**P4**
56	**In a typical week, on how many days do you do moderate-intensity activities as part of your work?** *Valid responses range from 1-7*	**Number of days**	**P5**
57	**How much time do you spend doing moderate-intensity activities at work on a typical day?** *Think of one day you can recall easily. Consider only those activities undertaken continuously for 10 minutes or more. Probe very high responses (over 4 hrs) to verify.*	**Hours : minutes** hrs mins	**P6 (a-b)**

Travel to and from places

The next questions exclude the physical activities at work that you have already mentioned.

Now I would like to ask you about the usual way you travel to and from places. For example to work, for shopping, to market, to place of worship. [insert other examples if needed]

The introductory statement to the following questions on transport-related physical activity is very important. It asks and helps the participant to now think about how they travel around getting from place-to-place. This statement should not be omitted.

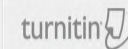| 58	Do you walk or use a bicycle (*pedal cycle*) for at least 10 minutes continuously to get to and from places? *Circle the appropriate response.*	Yes 1 No 2 *If No, go to P 10*	P7
59	In a typical week, on how many days do you walk or bicycle for at least 10 minutes continuously to get to and from places? *Valid responses range from 1-7*	**Number of days**	P8

Participant Identification Number

60	How much time do you spend walking or bicycling for travel on a typical day? *Think of one day you can recall easily. Consider the total amount of time walking or bicycling for trips of 10 minutes or more. Probe very high responses (over 4 hrs) to verify.*	Hours : minutes hrs mins	P9 (a-b)

Recreational activities			
The next questions exclude the work and transport activities that you have already mentioned. **Now I would like to ask you about sports, fitness and recreational activities (leisure),[insert relevant terms].** *This introductory statement directs the participant to think about recreational activities. This can also be called discretionary or leisure time. It includes sports and exercise but is not limited to participation competitions. Activities reported should be done regularly and not just occasionally. It is important to focus on only recreational activities and not to include any activities already mentioned. This statement should not be omitted.*			

Question		**Response**	**Code**
61	Do you do any vigorous-intensity sports, fitness or recreational (*leisure*) activities that cause large increases in breathing or heart rate like [*running or football,*] for at least 10 minutes continuously? *Activities are regarded as vigorous intensity if they cause a large increase in breathing and/or heart rate.* [INSERT EXAMPLES] (USE SHOWCARD)	Yes 1 No 2 *If No, go to P 13*	P10
62	In a typical week, on how many days do you do vigorous-intensity sports, fitness or recreational (*leisure*) activities? *Valid responses range from 1-7.*	Number of days	P11
63	How much time do you spend doing vigorous-intensity sports, fitness or recreational activities on a typical day? *Think of one day you can recall easily. Consider the total amount of time doing vigorous recreational activities for periods of 10 minutes or more. Probe very high responses (over 4 hrs).*	Hours : minutes hrs mins	P12 (a-b)
64	Do you do any moderate-intensity sports, fitness or recreational (*leisure*) activities that causes a small increase in breathing or heart rate such as brisk walking,(*cycling, swimming, volleyball*)for at least 10 minutes continuously? *Activities are regarded as moderate intensity if they cause a small increase in breathing and/or heart rate.* [INSERT EXAMPLES] (USE SHOWCARD)	Yes 1 No 2 *If No, go to P16*	P13
65	In a typical week, on how many days do you do moderate-intensity sports, fitness or recreational (*leisure*) activities? *Valid responses range from 1-7*	Number of days	P14
66	How much time do you spend doing moderate-intensity sports, fitness or recreational (*leisure*) activities on a typical day? *Think of one day you can recall easily. Consider the total amount of time doing moderate recreational activities for periods of 10 minutes or more. Probe very high responses (over 4 hrs).*	Hours : minutes hrs mins	P15 (a-b)

EXPANDED: Physical Activity

Sedentary behavior

The following question is about sitting or reclining at work, at home, getting to and from places, or with friends including time spent sitting at a desk, sitting with friends, traveling in car, bus, train, reading, playing cards or watching television, but do not include time spent sleeping.

[INSERT EXAMPLES]   (USE SHOWCARD)

67	**How much time do you usually spend sitting or reclining on a typical day?** *Consider total time spent at work sitting, in an office, reading, watching television, using a computer, doing hand craft like knitting, resting etc. Do not include time spent sleeping.*	**Hours : minutes** **hrs** **min s**	**P16 (a-b)**

Compliance to treatment among Type II diabetics receiving care at peripheral mobile clinics in Kaniyambadi block of Vellore district.

By

Dr. Divya Muliyil

A DISSERTATION SUBMITTED AS A PARTIAL FULFILMENT OF THE MD BRANCH XV (COMMUNITY MEDICINE) COURSE AS REQUIRED BY THE TAMIL NADU DR. MGR MEDICAL UNIVERSITY,CHENNAI FOR THE EXAMINATION TO BE HELD IN APRIL, 2013.

1

CERTIFICATE

This is to certify that the dissertation titled "COMPLIANCE TO TREATMENT AMONG TYPE II DIABETICS RECEIVING CARE AT PERIPHERAL MOBILE CLINICS IN KANIYAMBADI BLOCK OF VELLORE DISTRICT" is a bonafide work of Dr. Divya