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Impact of Clinical Pharmacist on Improving Medication Adherence among Type-2 Diabetes Mellitus Patients in Tertiary Care Teaching Hospital, Sangareddy: A Prospective - Interventional Study

M.Anusha[1], P. Hanah Priyadarshini[2], Syed Mohammed Siraj Ahmed[3], Meraj Siddiqua[4], Shaik Najeeb[5], Nafees Fathima[6], B. Deepika[7]

[1*]Assistant Professor, Department of Pharmacy Practice, Arya college of pharmacy, sanga reddy, kandi
[2,3,4,5]Student at Arya college of pharmacy, sanga reddy, kandi
[6,7]Assistant Professor, Department of Pharmacy Practice, Arya college of pharmacy, sanga reddy, kandi

***Corresponding author E-mail**: nellutla.jhancy@gmail.com

ABSTRACT

BACKGROUND

According to IDF Atlas 10th edition Diabetes prevalence is increasing Globally. 537 million adults (20-79 years) are living with diabetes -1 in 10. This number is predicted to rise to 643 million by 2030 and 783 million by 2045. Medication adherence is a major universal factor influencing patient health out-comes, particularly in chronic conditions such as Diabetes. Non- adherence or Poor adherence to anti diabetic medications can cause therapeutic failure, leading to manifestation of diabetes- related complications such as retinopathy, nephropathy, neuropathy etc., reduced quality of life and increased health care costs. To forestall these, likely predictors of medication non- adherence should be assessed and addressed appropriately. The purpose of this study was therefore, to assess medication adherence among type 2 diabetes mellitus patients and to identify the patient characteristics and probable factors associated withmedication non- adherence.

AIM

To evaluate the impact of clinical pharmacist on improving medication adherence among Type-2 Diabetes Mellitus patients.

OBJECTIVES

To identify the complications, To identify the factors associated with medication non- adherence, To provide effective patient counselling, To assess medication adherence adopted before and after counselling.

METHODOLOGY

A Prospective- Interventional study was carried out at Tertiary care teaching Hospital, Sangareddy, A structured proforma was designed to collect patient data. Morisky medication adherence scale was used to assess the patient medication adherence towards occurrence of diabetes. Complications and Factors associated with medication non-adherence were identified. Patient were provided with patient

counselling about disease, medication adherenceand life style modifications.

RESULTS

A Total of 108 Patient's with Type 2 Diabetes Mellitus were included in the study. Out of 108patients diagnosed with type-2 diabetes mellitus, 56 patients with (51.86%) were found to be female and 52 patients with (48.14%) were found to be male. Age group- 20-40 years of age group with (8%) followed by 41-60 years of age group with (60%) and age group of 61-80 years with (32%).Educational status- 42 (39%) patients were found to be illiterate followed by26 (24%) patients are primary school, 23 (21%) patients were found to be secondary school and 17 (16%) patients are higher education. Social history- 42 (39%) patients are smokers, 26(24%) patients are alcoholics followed by 23 (21%) patients are both alcoholic and smoker and 17 (16%) patients were found to be non-smoker and non-alcoholic. Complications-93% of thestudy population reported microvascular complications. Comorbidities- 65% of the patients were found to be Hypertensive which is the common comorbid condition observed in most of the Diabetes patients. Main reason for non- adherence was Forgetfulness (18%). Ant -diabetic therapy - 66 (61%) diabetic patients were prescribed with one anti diabetic drug, 42 (39%) diabetic patients were using combination therapy. Z- Test was done which revealed that the GRBs level reduced after the intervention from 241±103.2 to 160±38 and the HbA1c levels reduced after the intervention from 6.52±0.82 to 5.47±0.23 and it is stastistically significant with p=0< 0.05. Medication adherence - 64 patients with (59%) were found to be low adherence, 30 patients with (28%) are moderate adherence and 14 patients with (13%) are high adherence before follow up. After follow up the low adherence reduced to 4 patients with (4%),moderate adherence to 23 patients with (21%) and high adherence shown high improvement among 81 patients with (75%).

CONCLUSION

The study concludes that patient counselling found to have the significant influence in improving patient's medication adherence. ANOVA Test was applied to assess the difference in medication adherence score and we got p- value 0 so p< 0.05, hence there is statistically significant difference in medication adherence score in patients with Diabetes mellitus before and after follow-up and also the current study revealed that there is improvement in GRBS level as well as HbA1c levels after the follow up indicating that clinical pharmacist plays a vital role in the management of Type-2 Diabetes mellitus patients.

INTRODUCTION

1.1. Definition

Diabetes is a group of metabolic disease characterized by hyperglycemia resulting from defectsin insulin secretion, insulin action or both. Which leads overtime to serious damage to heart, blood vessels, eyes, kidneys and nerves.

1.2. Epidemiology

The **IDF Diabetes Atlas 10th edition** reports a continued global increase in diabetes prevalence, confirming diabetes as a significant global challenge to the health and well-being of individuals, families and societies.

Diabetes around the world in 2021:

- **537 million** adults (20-79 years) are living with diabetes- 1 in 10. This number is predicted to raise to **643 million** by 2030 and **783 million** by 2045.
- **Over 3 in 4** adults with diabetes live in low and middle-income countries.
- Diabetes is responsible for **6.7 million** deaths in 2021-1 in every 5seconds.
- Diabetes caused at least **USD 966 billion** dollars in health expenditure- a 316% increase overthe last 15 years.
- **541 million** adults have impaired glucose tolerance (IGT), which places them at high risk of diabetes.
- **Impact of clinical pharmacist on improving medication adherence among Type- 2 Diabetes mellituspatients in Tertiary care teaching Hospital, Sangareddy: A Prospective- Interventional study.**

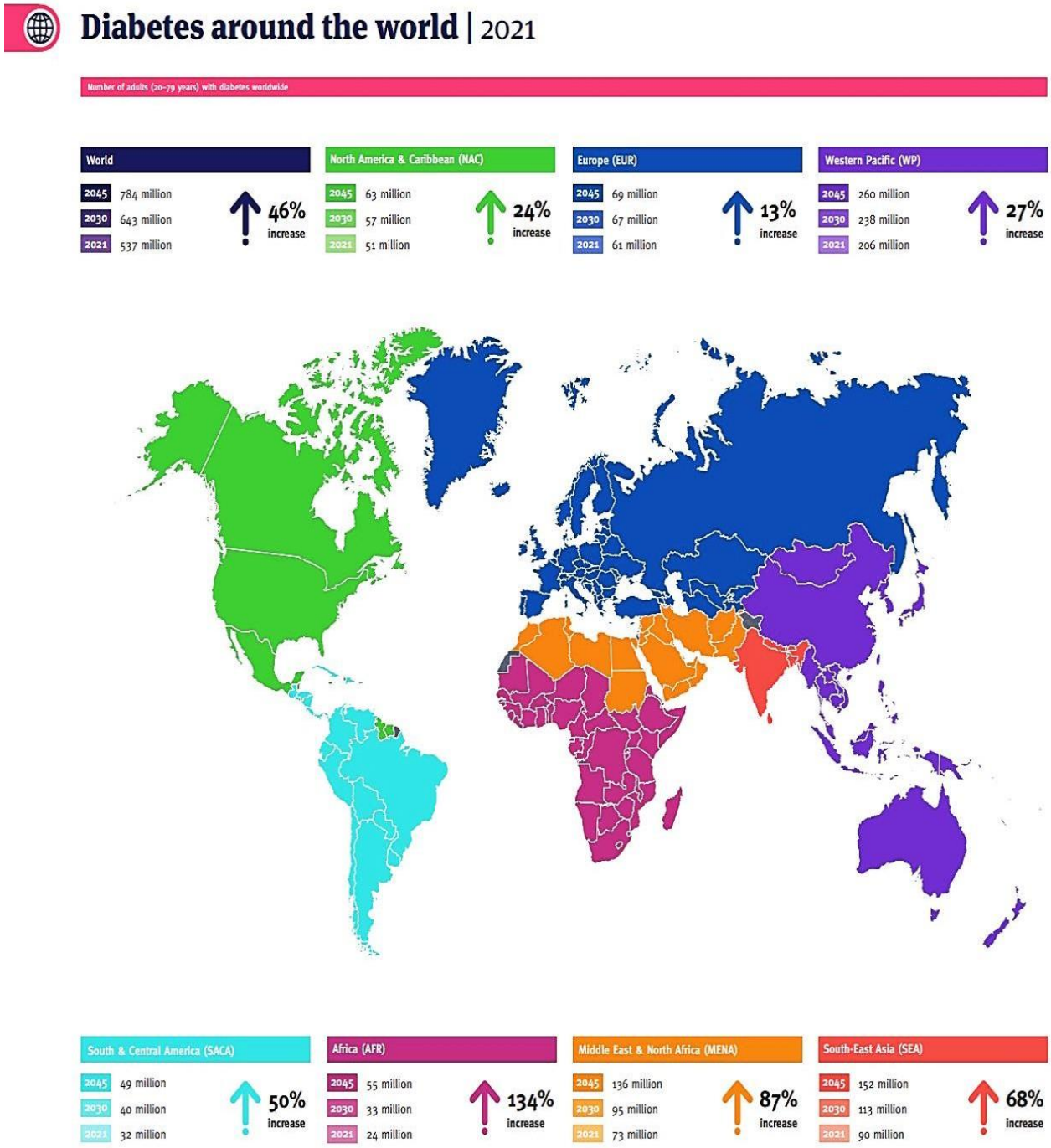


Figure 1.2.1: Global Epidemiology of Diabetes

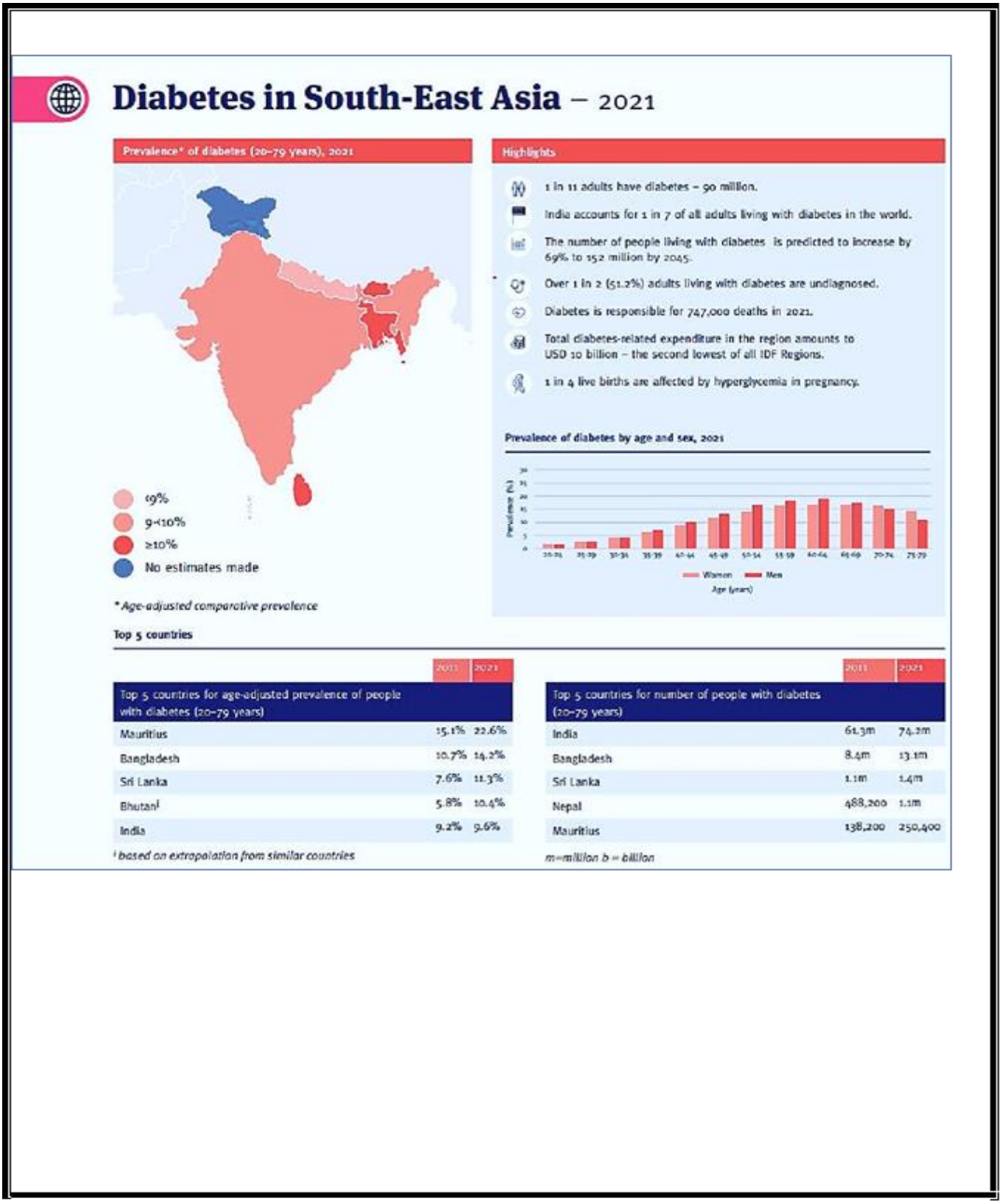
Source: International Diabetes Federation. IDF Diabetes Atlas 10th edn. Brussels,Belgium: International Diabetes Federation, 2021

Table 1.2.1: Top 10 countries or territories for number of adults (20-79years) with diabetes in 2021 and 2045

2021			2045		
Rank	**Country or territory**	**Number of peoplewith Diabetes (millions)**	**Rank**	**Country or territory**	**Number ofpeople with Diabetes (millions)**
1	**China**	**140.9**	**1**	**China**	**174.4**
2	**India**	**74.2**	**2**	**India**	**124.9**
3	**Pakistan**	**33.0**	**3**	**Pakistan**	**62.2**
4	**United Statesof America**	**32.2**	**4**	**United states of America**	**36.3**
5	**Indonesia**	**19.5**	**5**	**Indonesia**	**28.6**
6	**Brazil**	**15.7**	**6**	**Brazil**	**23.2**
7	**Mexico**	**14.1**	**7**	**Bangladesh**	**22.3**
8	**Bangladesh**	**13.1**	**8**	**Mexico**	**21.2**
9	**Japan**	**11.0**	**9**	**Egypt**	**20.0**
10	**Egypt**	**10.9**	**10**	**Turkey**	**13.4**

Source: International Diabetes Federation. IDF Diabetes Atlas 10th edn. Brussels,Belgium:International Diabetes Federation, 2021

Figure 1.2.2: India Epidemiology of Diabetes



Source: International Diabetes Federation. IDF Diabetes Atlas 10th edn. Brussels, Belgium: International Diabetes Federation, 2021

1.3. Types of Diabetes Mellitus

Assigning a type of diabetes to an individual often depends on the circumstances present at the time of diagnosis, and many diabetic individuals do not easily fit into a single class.

A. Type-1 Diabetes Mellitus

Type-1 Diabetes Mellitus results with Beta cell destruction usually leading to absolute insulin deficiency.

a) Immune mediated diabetes

This form of diabetes, accounts for only 5% of those with diabetes. Type-1 Diabetes Mellitus, or juvenile onset diabetes, results from a cellular mediated autoimmune destruction of the beta cells of the pancreas.

b) Idiopathic diabetes

This form of type-1 diabetes mellitus have unknown etiologies. These patients may show permanent insulinopenia and are prone to Ketoacidosis.

B. Type-2 Diabetes Mellitus

This form of diabetes accounts for 90-95% of those with diabetes. Most patients with form of diabetes is obese and obesity itself leads to insulin resistance. This form of diabetes mellitus commonly goes undiagnosed for several years because hyperglycemia develops slowly and at early stages is often not severe enough for the patient to notice any symptoms of diabetes. The risk of developing this form of diabetes increase with age obesity and lack of physical activity it also occurs more commonly in women who have previously diagnosed with GDM.

C. Gestational Diabetes Mellitus

GDM is defined as any degree of GIT with onset or first recognition during pregnancy.

D. Other types

a. Genetic defects of the beta cell
b. Genetic defects in insulin action
c. Disease of the exocrine pancreas
d. Endocrinopathies
e. Drug or chemical induced diabetes
f. Infections
g. Unknown forms of immune mediated diabetes

1.4. Pathophysiology

TYPE-2 DIABETES MELLITUS

In the etiology of T2DM genetic factors play important role. Identical twins revealing 10% risk for developing T2DM. Diabetic genotype influenced by the various factors among them main factor is obesity and other factors such as low physical activity, dietary habits [high intake of carbohydrates, low fiber intake], stress life show great impact on developing T2DM.

Genesis of T2DM involves in 2 abnormalities.

a) Impaired Insulin Secretion [IIS]

❖ IIS is a decrease in glucose responsiveness which is observed before the clinical onset of disease.

❖ IGT is induced by reduced glucose responsiveness in early phase of insulin secretion and decreased further insulin secretion post meals causes Post Prandial Hyperglycemia.

❖ IIS is generally progressive and this progression involves glucose toxicity and lipotoxicity.

❖ If IIS left untreated it may leads to permanent elevation of blood glucose.

b) Insulin resistance

❖ Insulin resistance is condition in which insulin in the body is not show sufficient action to its blood concentration.

❖ The impairment of insulin action major target organs such as liver and muscles is a common pathophysiological feature of T2DM.

❖ Insulin resistance is mainly associated with obesity, genetic factors and poor lifestyle.

❖ A convenient way to estimate the degree of resistance is to check for the presence of high fasting blood insulin, visceral obesity, hypertriglyceridemia etc.

1: Symptoms of Diabetes

❖ Acute metabolic deterioration and/or acute presentation of chronic complications

❖ Severe dehydration

❖ Altered level of consciousness

❖ Diabetic complications, which usually occur after years of having the disease, including acute coronary disease, stroke, kidney disease, vision loss and diabetic foot.

1.5. Diagnostic criteria

Test Criteria	Normal Values	Prediabetes	Diabetes
Glycosylated hemoglobin (HbA1c)	**< 5.7%**	**5.7 to 6.4%**	**> 6.5% or higher**
Fasting Plasma Glucose (FPG)	**< 100 mg/dl**	**100-125 mg/dl**	**>126 mg/dl orhigher**
Post Prandial Plasma Glucose (PPG)	**70-140 mg/dl**	**140-199 mg/dl**	**>200 mg/dl**
Random Plasma Glucose (RPG)	**70-140 mg/dl**	**140-200 mg/dl**	**>200mg/dl**
Oral Glucose Tolerance Test (OGTT)	**< 140 mg/dl**	**140-199 mg/dl**	**>200mg/dl orhigher**

Table 1.6.1: Diabetes Criteria

Source: American Diabetes Association; Standards of Medical Care in Diabetes— 2022 Abridged for Primary Care Providers. Clin Diabetes 1 January 2022; 40 (1)

Introduction

1.6. Complications

Diabetes complications are classified in to two major types

A. Acute complications: Hypoglycemia that may result from DKA [Diabetic Ketoacdosis] or HHNS [Hyperosmolar Hyperglycemic Non Ketotic syndrome]

B. Chronic complications: Microvascular such as Diabetic Retinopathy, Nephropathy, Neuropathy or macrovascular such as Coronary Artery Disease, Stroke, Peripheral arterial disease

❖ Acute complications

There are three major acute complications of diabetes related to the short-term imbalancesin blood glucose level.

- Hypoglycemia [abnormally low blood glucose level]
- DKA [Diabetic Ketoacidosis]
- HHNS [Hyperglycemic Non-Ketotic coma or Hyperglycemic Hyperosmolar syndrome]

❖ Chronic complications

a) Microvascular complications

b) Macrovascular complications

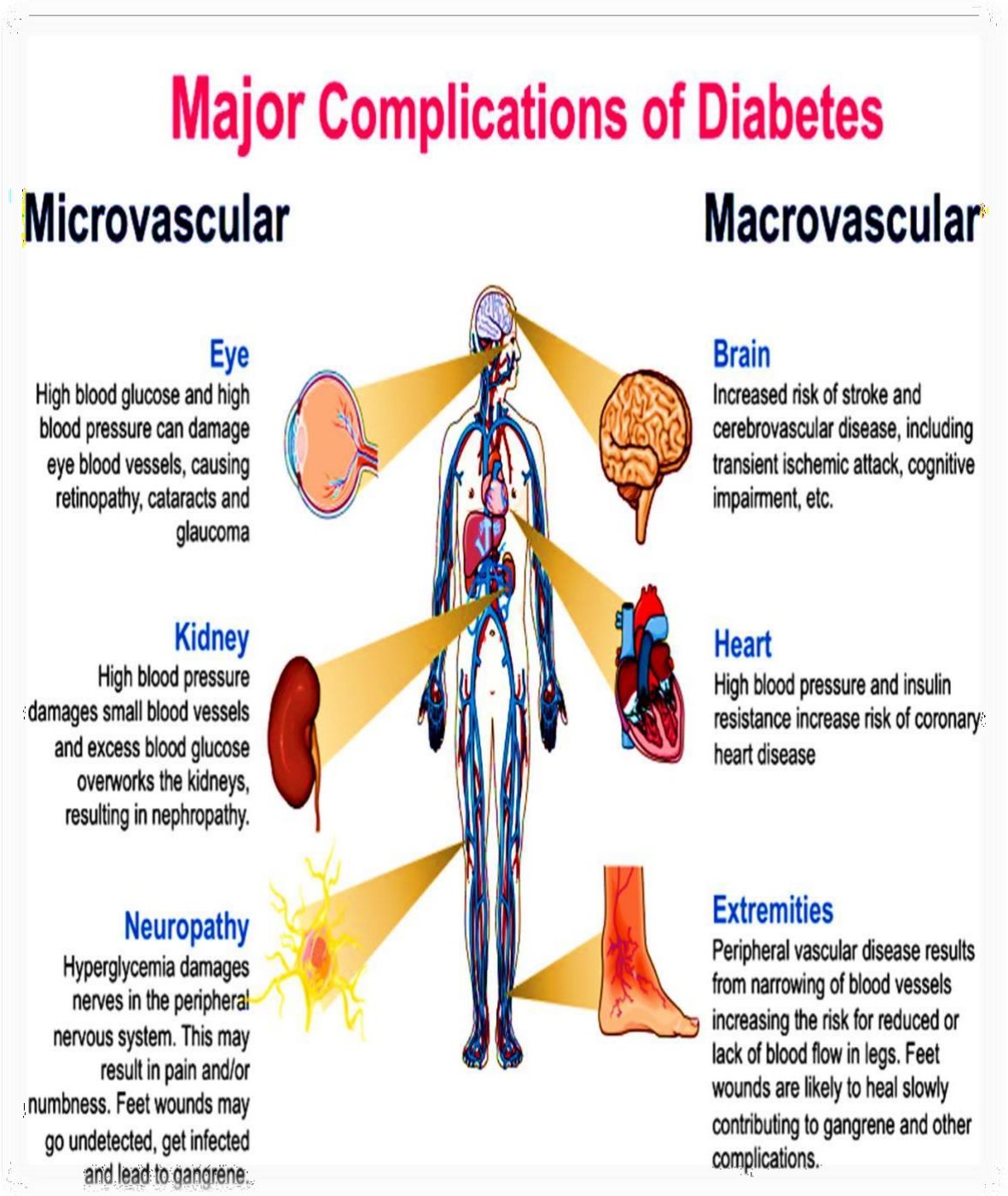


Figure 1.7.1: Major Complications of Diabetes

1.7. Risk factors

Modifiable risk factors

Obese/overweight: Being overweight or obese increases risk of developing T2DM. In obese individual, the amount of non-esterified fatty acids, glycerol, hormones, cytokines, pro-inflammatory markers, and other substance that involved in the development of insulinresistance is increased.

Physical inactivity: Physical inactivity is a key modifiable risk factor for prediabetes and type-2 diabetes.

Hypertension: Patient with hypertension often exhibit insulin resistance and are at greater riskof diabetes developing than are normotensive individuals.

Smoking: Smoking can cause severely aggravated glucose tolerance and the insulin sensitivity index. Insulin insensitivity occurs from nicotine that is one of the active chemicals in cigarettes. Nicotine can cause diabetes.

Diet: A diet high in fat, calories, and cholesterol increases risk of diabetes.

Alcohol: Heavy use of alcohol can cause inflammation in the pancreas and limit is ability to produce enough insulin.

Introduction

Non-Modifiable risk factors

Family history: some factors that increase the risk of diabetes are inherited from parents or close biological relatives. Diabetes susceptibility genes are CAPN10 and ACRP30. But these results did not show consistency throughout entire population. So these genes could not be definitely concluded as high risk factors for T2DM.

Race or ethnic background: People from black African, African Caribbean and south Asian (Indian, Pakistani, Bangladeshi) backgrounds are at a higher risk of developing T2DM from ayounger age.

Age: Chances of T2DM increase with increase in age. Human body gets less sensitive to insulin as it ages and the beta-cells get altered or show insufficient in insulin production as the human body ages. According to the National Diabetes Statistics Report of the United States of America, they found that 4.0% of people are having diabetes in the age group of 18-44 years,and 17.0% in45-65 years of age, and 25.2% for ≥65 years of age.

Gestational Diabetes: If diabetes during pregnancy, are at increased risk of developing diabetes again later in life.

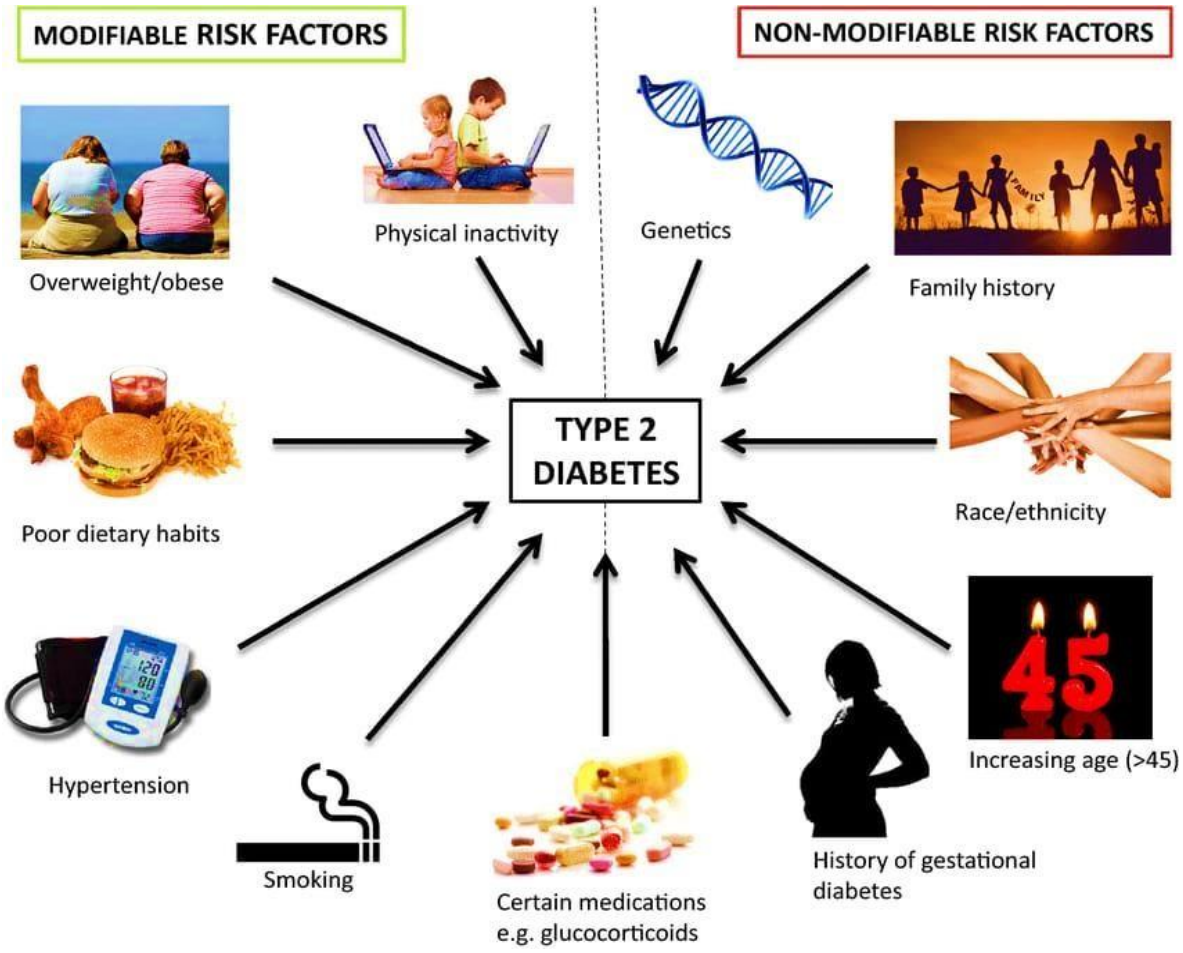


Figure 1.8.1: Risk factors

1.8. Management of Type-2 Diabetes Mellitus

Non pharmacologic therapy*:*

Non pharmacologic therapy such as medical nutrition therapy (MNT), physical activity, and diabetes self-management education (DSME) is a corner stone of treatment for all patients withdiabetes.

Medical nutrition therapy:

- ❖ A healthy meal plan that is moderate in calories and carbohydrates and low in saturated fat (i.e., less than 7% of total calories) with all of the essential vitamins and minerals is recommended.
- ❖ Carbohydrate intake from vegetables fruits, legumes, whole grains, dairy products and those high in fibers is preferred.
- ❖ Mediterranean- style diet rich in mono and poly-unsaturated fats may have glucose and CV benefits and could be considered.
- ❖ Weight loss or weight maintenance is a crucial element in many patients with type-2 DM.
- ❖ Sugar-sweetened beverages and foods with added sugars should be discouraged.
- ❖ Discourage bed time and between-meal snacks, set realistic goals.

Physical activity:

❖ Aerobic exercise improves insulin sensitivity, modestly improves glycemic control in the majority of the individuals, reduces CV risk, contributes to weight loss or maintenance and improves well-being.

❖ Physical activity goals include at least 150 mins per week.

Introduction

Diabetes non pharmacological self-management education and support (DSME/S):

❖ The American Association of Diabetes Educators (AADE) has identified seven self-care behaviors that can be targeted through DSME/S. The behaviors include healthy eating, being active, monitoring, taking medications, problem-solving, reducing risk and healthy copying.

❖ Patients are advised not to smoke, and smoking cessation counselling should be a routine component of diabetes care.

1.8.1. Pharmacological treatment:

The **American Diabetes Association (ADA)** "Standards of Medical Care in Diabetes" includes the ADA's current clinical practice **recommendations** and is intended to provide thecomponents of diabetes care, general treatment goals and guidelines, and tools to evaluate quality of care.

- Metformin is the preferred initial pharmacologic agent for the treatment of type 2 diabetes.
- An ACE inhibitor (ACEi) or Angiotensin receptor blocker (ARB) is suggested to treat hypertension for Patient's with Diabetes Mellitus who are having coronary artery disease or urine albumin-to- creatinine ratio 30-299mg/g creatinine.
- SGLT-2 inhibitors are now recommended to treat heart failure and can be started at the time of diagnosis
- Finerenone can be used to treat CKD when SGLT-2 inhibitors are not well tolerated.
- Combination therapy may be considered for people with established heart/ kidney disease. ADA recommends that people with type 2- Diabetes Mellitus who take insulin combine insulin with GLP-1 receptor agonists.
- Over weight or obesity therapy recommendations now include Wegovy (semaglutide 2.4 mg)as an effective therapy for weight management of people with Type -2 Diabetes Mellitus.
- Among patients with type 2 diabetes who have established atherosclerotic cardiovascular disease or indicators of high risk, established kidney disease, or heart failure, a sodium–glucose cotransporter 2 inhibitor or glucagon-like peptide 1 receptor agonist with demonstrated
- cardiovascular disease benefit is recommended as part of the glucose-lowering regimen independent of A1C and in consideration of patient-specific factors.
- The medication regimen and medication-taking behavior should be reevaluated at regular intervals (every 3–6 months) and adjusted as needed to incorporate specific factors that impactchoice of treatment.

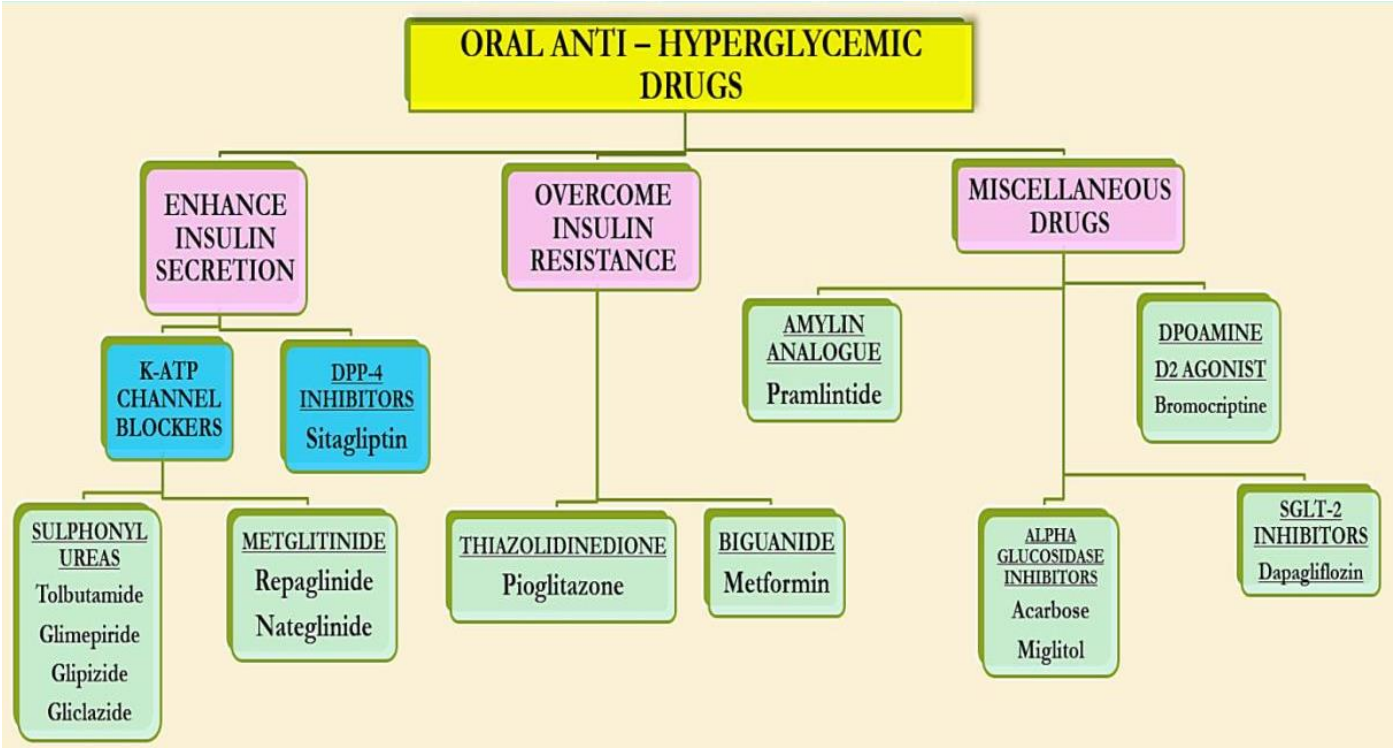


Figure 1.9.2.1: Oral Anti- Hyperglycemic Drugs

Insulin therapy

Insulin is a hormone released by the beta cells of the pancreas that promotes glucose metabolism.it is the mainstay of therapy in type 1 diabetes. However, many patients with type 2diabetes will also require insulin injections to help to achieve their glycemic targets.

Indications for the use of insulin in type 2 diabetes mellitus at the time of diagnosis or other situations:

- ❖ Person with diabetes with significant, symptomatic hyperglycemia, loss of weight, and polyuria, polydipsia, polyphagia.
- ❖ Fasting plasma glucose >270mg/dl or HbA1c >9%.
- ❖ Presence of ketosis, Hyperosmolar state /lactic acidosis.
- ❖ Patients not responding to optimal doses of OHA alone or combinations.
- ❖ Pre- operative state, Hepatic or renal failure.
- ❖ Stressful situations such as acute myocardial infarction, stroke, acute infections, tuberculosis, trauma and other conditions requiring hospitalization.

Types of insulin

Types of Insulin	Onset	Peak	Duration	Examples
Rapid acting	35 minutes	1-2 hours	2-4 hours	Aspart, Glulisine, lispro
Regular or short acting	30 minutes	2-3 hours	3-6 hours	Human regular
Intermediate acting	2-4 hours	4-12 hours	12-18 hours	NPH
Long acting	2 hours	Does notpeak	Up to 24 hours	Degludec, Glargine
Ultra- long acting	6 hours	Does not peak	36 hours or more	Glargine U-300

Table 1.8.2.1: Types of Insulin

1.8.2. Special populations

Prediabetes and preventing type-2 diabetes mellitus

❖ Weight loss, regular aerobic activity, increased fiber intake and limiting fat consumption arethe four life-style pillars for both the treatment and prevention of type-2 diabetes mellitus.

❖ The ADA recommended metformin in conjunction with life-style changes to delay the onsetof diabetes in patients with pre diabetes, particularly those with a BMI > 35 kg/m², those aged < 60 years and women with a history GD.

Children and adolescence with type-2 diabetes

❖ The only FDA-approved oral agent for the treatment of type-2 diabetes mellitus in children (10-16 yrs of age) is metformin and similar to adult guidelines, some experts recommended itsroutine use in the absence of contraindications.

❖ Insulin therapy continuous to be the standard of care when glycemic goals cannot be achievedor maintained with metformin mono therapy.

Older adults

❖ The number and severity of comorbid conditions, renal dysfunction, ability to engage in self-care, nutritional status, social support and life expectancy should all influence glycemic goals and treatment selections in older adults.

❖ While a decline in renal function may preclude the use of metformin in some older adults, lower doses may be used if coupled with more frequent monitoring of renal function when the estimated glomerular filteration rate is consistently above 30ml/min/1.73m².

❖ Alpha glucosidase inhibitors generally safe may also be used.

Patients with HIV

❖ Metformin is a drug of choice for HIV patients as weight gain can be minimized. Stavudine, zidovudine and didanosine may cause lactatemia, especially upon long-term use. It may be advisable to check lactate levels in patients taking these medications prior to metformin use.

Pregnant women

❖ In women with type-2 diabetes mellitus controlled by life-style modification alone, conversionto insulin is often necessary soon after pregnancy is confirmed.

❖ While NPH remains the recommended basal insulin to use during pregnancy

❖ In women with type-2 diabetes mellitus/ GDM, both metformin and glyburide have been studied as alternatives to insulin therapy.

Hospitalized Patients

❖ patients with diabetes are frequently admitted to hospitals for an acute illness or surgical procedure, so Insulin therapy is recommended if BG readings are persistently > 180 mg/dL.

❖ It is prudent to stop metformin in all patients as contraindications are common in hospitalized patients.

❖ Patients who require surgery, scheduled doses of insulin or continuous insulin infusions are preferred.

❖ For Patient's who can eat soon after surgery, basal insulin continuation is warranted.

4. RESULTS

A total of 108 subjects were enrolled in the study.

Table 5.0: Baseline Demographic Data of patient population

S.NO	PARAMETERS	NO. OF PATIENTS N=108	PERCENTGE(%)
1	**GENDER**		
	a. Male	52	48.14%
	b. Female	56	51.86%
2	**AGE**		
	a. 20-40 years	9	8%
	b. 41-60 years	65	60%
	c. 61-80 years	34	32%
3	**EDUCATIONAL STATUS**		
	a. Illiterate	42	39%
	b. Primary school	26	24%
	c. Secondary school	23	21%
	d. Higher education	17	16%
4	**SOCIAL HISTORY**		
	a. Smokers	16	15%
	b. Alcoholics	24	22%
	c. Both	7	7%
	d. none	61	56%

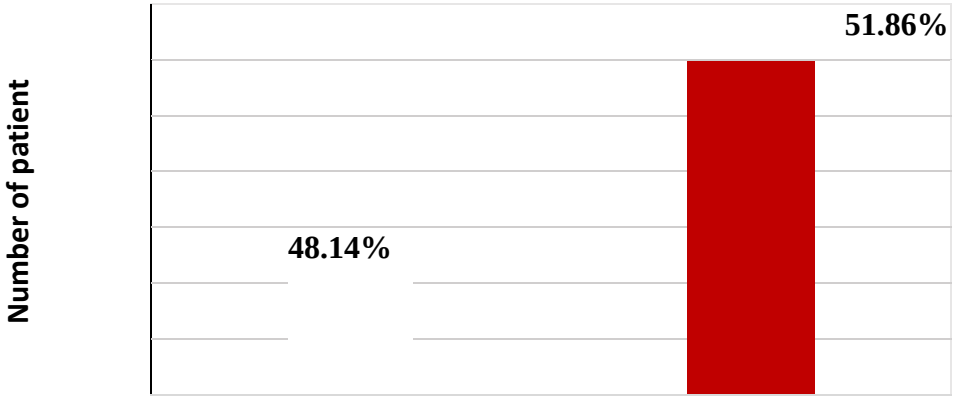
5	**COMPLICATIONS**		
	a. Neuropathy	71	50%
	b. Retinopathy	46	32%
	c. Nephropathy	16	11%
	d. Peripheral vascular disease	5	4%
	e. Cerebrovascular accident	4	3%
6	**COMORBIDITIES**		
	a. Hypertension	65	60%
	b. Obesity	15	13.8%
	c. Chronic renal failure	8	7.4%
	d. Diabetic foot	6	5.5%
	e. Hyperlipidemia	5	4.6%
	f. Chronic heart disease	4	3.7%
	g. Tuberculosis	3	3%
	h. COPD	2	2%
7	**DURATION OF DIABETES**		
	a. 1-5 years	26	24%
	b. 6-10 years	48	44%
	c. More than 10 years	34	32%
8	**ANTI- DIABETIC THERAPY**		
	a. Monotherapy	66	61%
	b. Combination therapy	42	39%

PARAMETER 1: Distribution of patients based on Gender

Gender	Total no of patientsN=108	Percentage (%)
Male	**52**	**48.14%**
Female	**56**	**51.86%**

Table 5.1: Distribution of patients based on Gender

Out of 108 patients diagnosed with type-2 diabetes mellitus, 56 patients with (51.86%) were found to be female and 52 patients with (48.14%) were found to be male. Female patients areat higher risk compared to male patients.



PARAMETER 2: Distribution of patients based on Age

Age	Total no of patientsN=108	Percentage (%)
20-40 years	**9**	**8%**
41-60 years	**65**	**60%**
61-80 years	**34**	**32%**

Table 5.2: Distribution of patients based on Age

Out of 108 patients, 9 patients were found in age group between 20-40 years of age with (8%)followed by 65 patients in the age group between 41-60 years with (60%) and 34 patients werefound in age group of 61-80 years with (32%). The age group which is of higher risk is 41-60years .

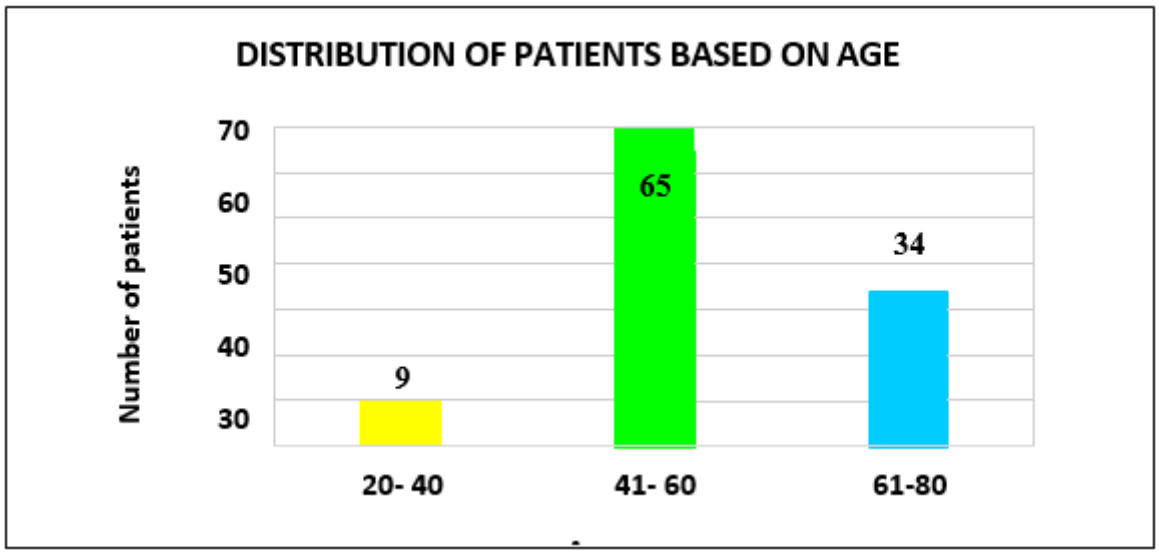


Figure: 5.2 Distribution of patients based on Age

PARAMETER 3: Distribution of patients based on educational status

Educational status	Total no of patientsN=108	Percentage (%)
Illiterate	42	39%
Primary school	26	24%
Secondary school	23	21%
Higher education	17	16%

Table 5.3: Distribution of patients based on educational status

Out of 108 patients, 42 patients with (39%) were found to be illiterate followed by 26 patientswith (24%) are primary school, 23 patients with (21%) were found to be secondary school and17 patients with (16%) are higher education. The illiterates are at low medication adherence.

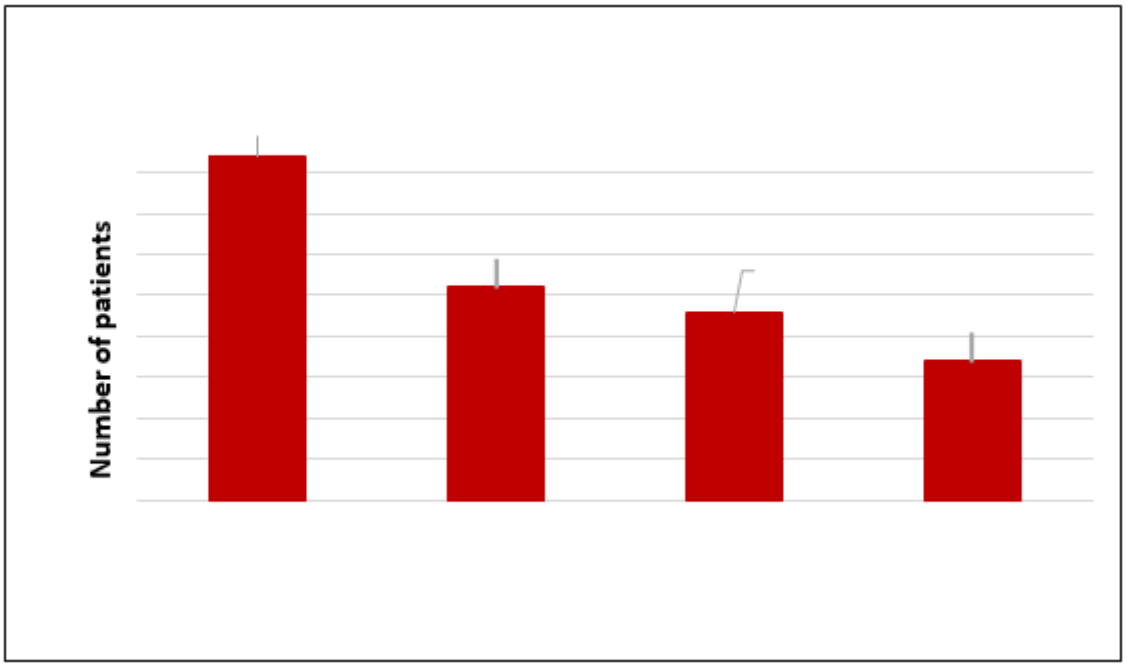


Figure 5.3: Distribution of patients based on educational status

PARAMETER 4: Distribution of patients based on social history

Social history	Total no of patientsN=108	Percentage (%)
Smokers	**16**	**15%**
Alcoholics	**24**	**22%**
Both	**7**	**7%**
None	**61**	**56%**

Table 5.4: Distribution of patients based on social history

Out of 108 patients, 16 patients with (15%) are smokers, 24 patients with (22%) are alcoholics followed by 7 patients with (7%) are both alcoholic and smoker and 61 patientswith (56%) were found to be non-smoker and non-alcoholic.

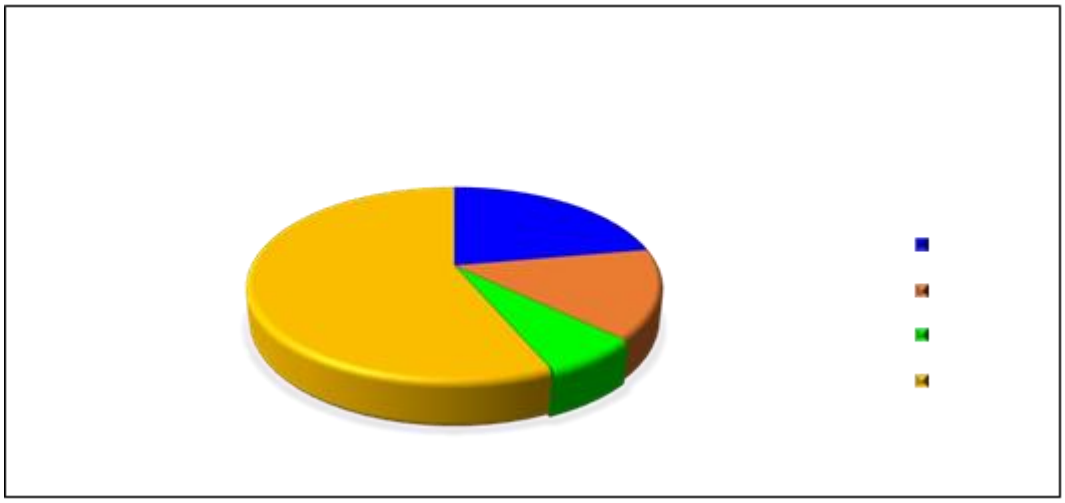


Figure 5.4: Distribution of patients based on social history

PARAMETER 5: Distribution of patients based on complications

Complications	Total no of patientsN=108	Percentage (%)
Neuropathy	71	50%
Retinopathy	46	32%
Nephropathy	16	11%
Peripheral vascular disease	5	4%
Cerebrovascular Accident	4	3%

Table 5.5: Distribution of patients based on complications

Out of 108 patients, 71 patients (50%) are with neuropathy, 46 patients (32%) are with retinopathy, 16 patients (11%) are with nephropathy, 5 patients (4%) are with peripheralvascular disease and 4 patients (3%) are with cerebrovascular accident.

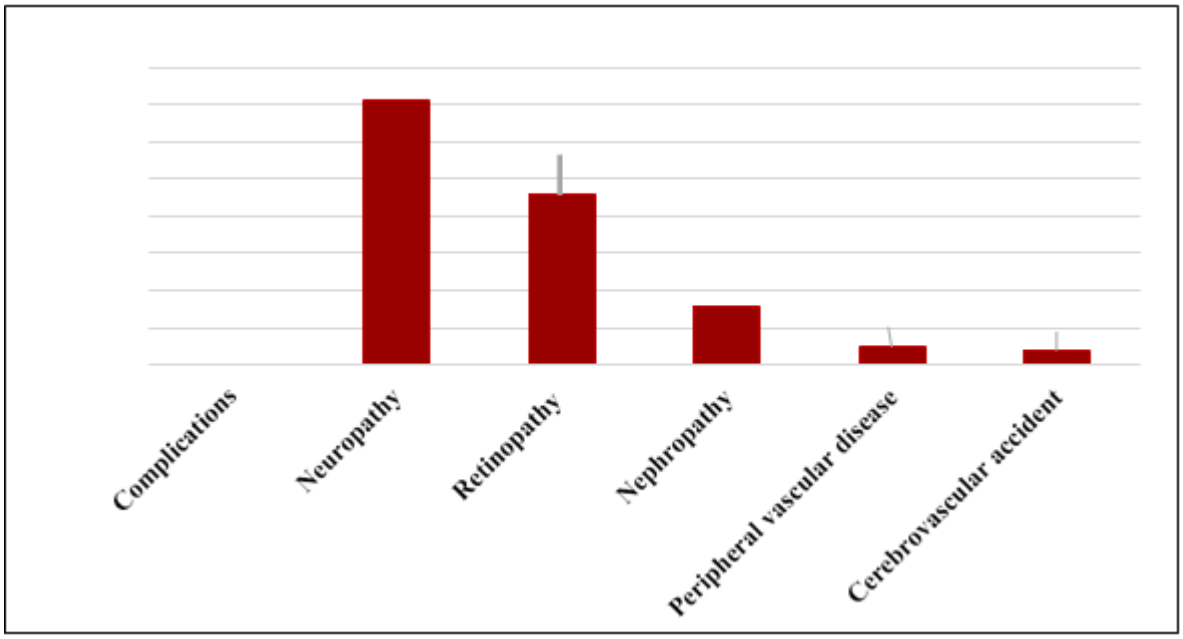


Figure 5.5: Distribution of patients based on complications

PARAMETER 6: Distribution of patients based on Co-Morbidities

Co- morbidities	Total no of patientsN=108	Percentage (%)
Hypertension	65	60%
Obesity	15	13.8%
Chronic renal Failure	8	7.4%
Diabetic Foot	6	5.5%
Hyperlipidemia	5	4.6%
Chronic heart disease	4	3.7%
Tuberculosis	3	3%
COPD	2	2%

Table 5.6: Distribution of patients based on Co-Morbidities

Out of 108 patients, 65(60%) patients are with hypertension, 15(13.8%) patients are obese, 8(7.4%) patients are with chronic renal failure, 6(5.5%) patients are with diabetic foot, 5 (4.6%)patients are with hyperlipidemia, 4 (3.7%) patients are with chronic heart failure,3 (3%) patients are with tuberculosis and 2 (2%) patients are with COPD. Hypertension is found in majority of people.

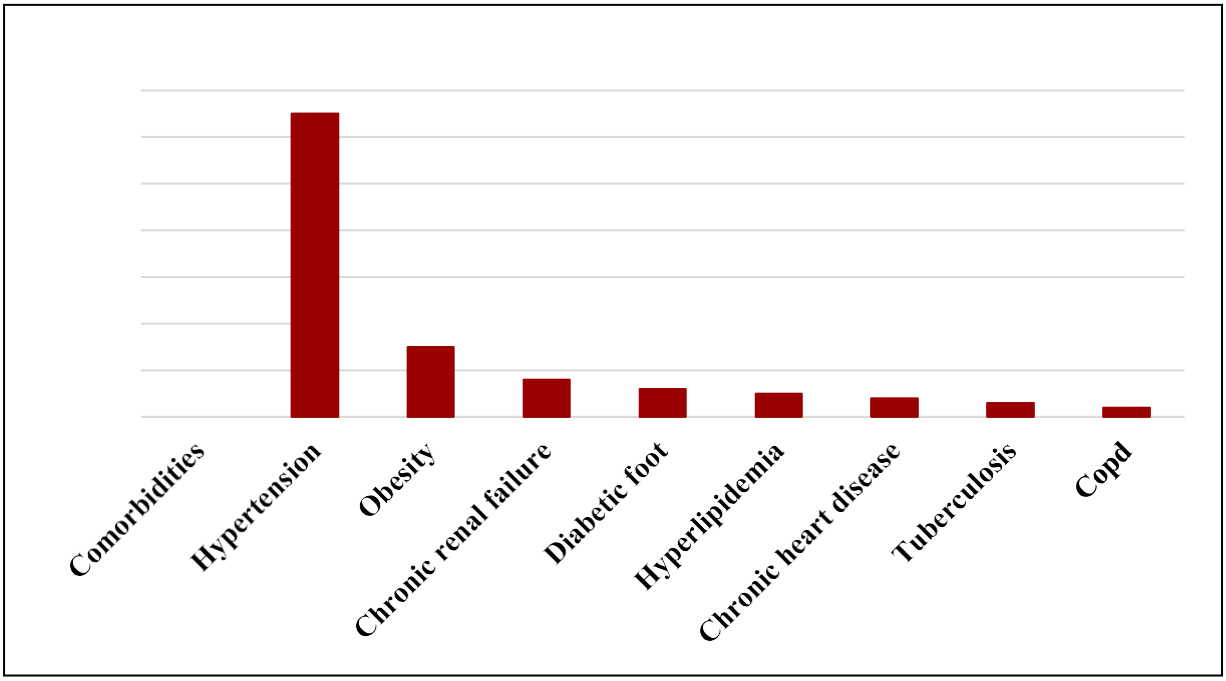


Figure 5.6: Distribution of patients based on Co-Morbidities

PARAMETER 7: Distribution of patients based on Duration of Diabetes

DURATION OFDIABETES	Total no of patientsN=108	Percentage (%)
1-5 years	26	24%
6-10 years	48	44%
More than 10 years	34	32%

Table 5.7: Distribution of patients based on Duration of Diabetes

Out of 108 patients, 26 patients with (24%) had been diagnosed with diabetes for the past 1-5years, 48 patients with (44%) had been diagnosed with diabetes for the past 5-10 years followed by 34 patients with (32%) had been diagnosed with diabetes for the past more than 10 years,

PARAMETER 8: Distribution of patients based on Anti- Diabetic Therapy

ANTI- DAIBETICTHERAPY	Total no of patientsN=108	Percentage (%)
Monotherapy	66	61%
Combination therapy	42	39%

Table 5.8: Distribution of patients based on Anti- Diabetic Therapy

Out of 108 patients, 66 diabetic patients with (61%) were prescribed with one anti diabetic drug, 42 diabetic patients with (39%) were using combination therapy.

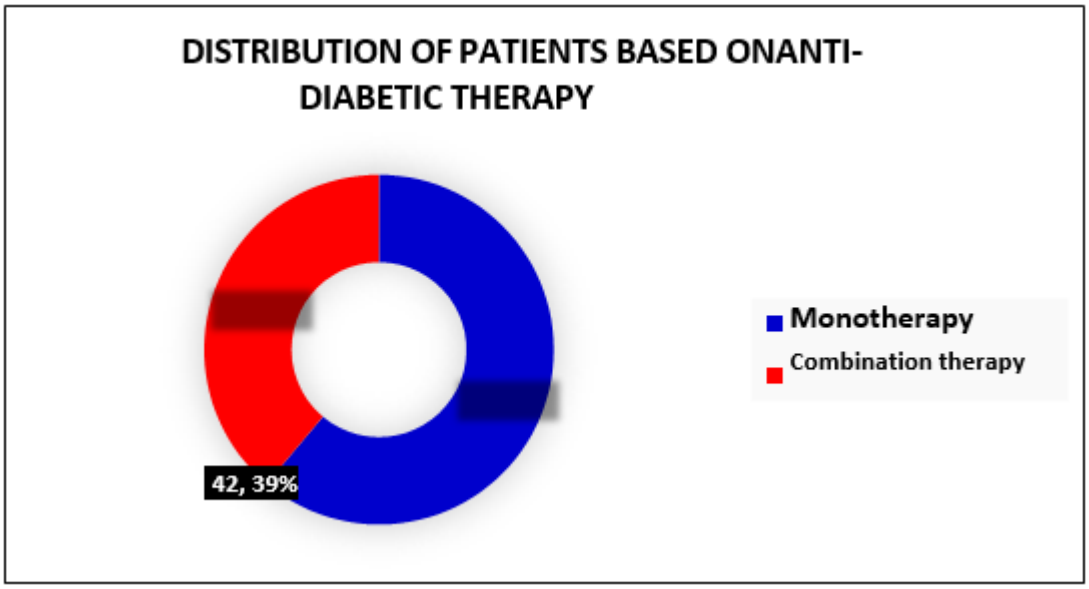


Figure 5.8: Distribution of patients based on Anti- Diabetic Therapy

PARAMETER 9: Factors associated with medication non-adherence

Factors	Total no ofpatients N=108	Percentage (%)
Forgetfulness	31	18%
Poor follow up	29	17%
Decrease in symptoms severity	26	15%
Polypharmacy	21	12%
Low health literacy	18	10 %
Busy schedule	16	9%
Poor communication between provider and patient	15	8%
depression	14	8%
Poor relationship between provider andpatient	3	2%
Duration of therapy	2	1%

Table 5.9: Factors associated with medication non-adherence

Out of 108 patients, 31 patients with (18%) are due to forgetfulness,29 patients with (17%) are due to poor follow up, 26 patients with (15%) are due to decrease in symptoms severity, 21 patients with (12%) are due to polypharmacy,18 patients with (10%) are due to low health literacy, 16 patients (9%) are due to busy schedule, 15 patients with (8%) are due to poor communication between provider and patient, 14 patients with (8%) are due to depression, 3 patients with (2%) are due to poor relationship between provider and patient and 2 patients with (1%) are due to duration of therapy.

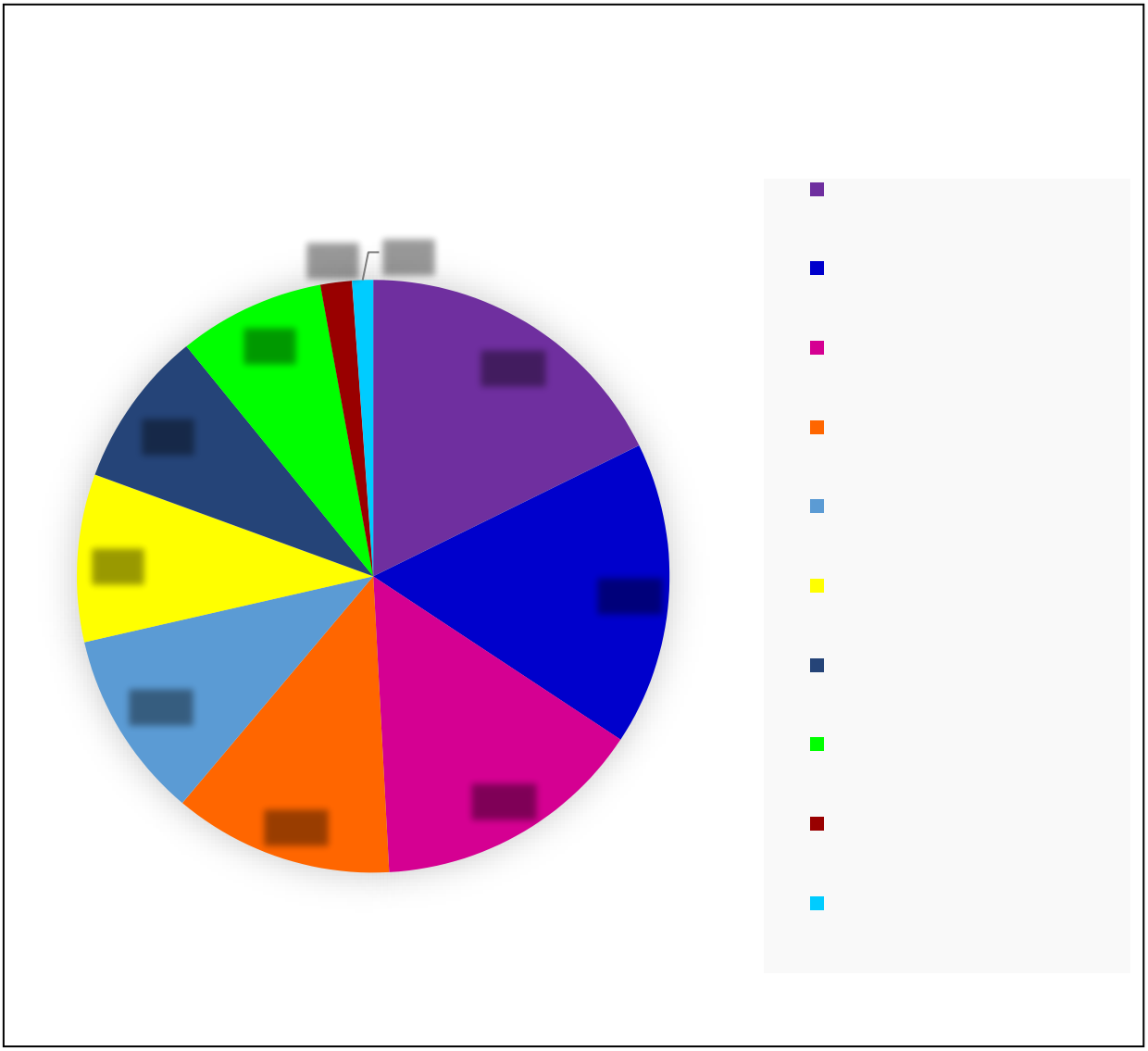


Figure 5.9: Factors associated with medication non-adherence

CHI-SQUARE ANALYSIS

PARAMETER 10: Relation between comorbid condition and occurrence of diabetes with respect to gender.

Comorbidities	Male	Female	Chi square	P value
Hypertension	31	34	0.19	0.65
Chronic Heartdisease	2	2	0	1
Renal failure	6	3	1.04	0.3
Obesity	9	6	0.64	0.42
Hyperlipidaemia	2	6	2.07	0.14
TB	1	2	0.33	0.56
HIV	0	1	1	0.31
COPD	0	1	1	0.31
CVA	0	1	1	0.31
Hypothyroidism	0	1	1	0.31

Table 5.10: Relation between comorbid condition and occurrence of diabetes with respect to gender.

- In this study, multiple comorbid conditions were observed in patients with Diabetes mellitus.
- Hypertension was the common comorbid condition observed in most of the Diabetes patients
- Chi-square test was applied to assess the relation between comorbid condition and occurrence of the Diabetes with respect to gender.
- P value of < 0.05 is considered as significant.
- Chi-Square test revealed that there exists no statistical significant relation between comorbid condition and occurrence of the Diabetes with respect to gender.

PARAMETER 11: Relation between diabetes and occurrence of complications in diabetes patients with respect to gender

Complications	Male	Female	Chi square	P value
Neuropathy	38	40	0.08	0.77
Nephropathy	8	7	0.07	0.7
Retinopathy	17	26	2.35	0.12
PVD	2	2	1	1
CVA	3	1	1.01	0.31

Table 5.11: Relation between diabetes and occurrence of complications in diabetes patients with respect to gender

- In this study, multiple complications were observed in patients with Diabetes mellitus.
- Neuropathy was the common complication observed in most of the Diabetes patients
- Chi-square test was applied to assess the relation between Diabetes and occurrence of complications in diabetes patients with respect to gender.
- P value of <0.05 is considered as significant.
- Chi-Square test revealed that there exists no statistical significant relation between Diabetes and occurrence of complications in diabetes patients with respect to gender.

Z – TEST OF SIGNIFICANCE (GRBS)

PARAMETER 12: Changes in GRBS by comparing before and after follow up – Z test

GRBS	Before Follow up	After Follow up
Mean (mg/dl)	241	160
Std. Dev	103.2	38

Table 5.12: Changes in GRBS by comparing before and after follow up – Z test

Out of 108 patients the GRBS level reduced after the intervention from 241±103.2 to 160±38 which was statistically significant with $p<0.05$.

(1) Null and Alternative Hypothesis
The following null and alternative hypotheses need to be tested:

Null
There is no difference in GRBS before follow up and after follow up in diabetes patients.

Alternative
There is decrease in GRBS after follow up in diabetes, which indicates that patients had used medications regularly.

(2) Rejection Region
Based on the information provided, the significance level is \alpha = 0.05α=0.05, and the critical value for a two-tailed test is Zc = 1.96.
The rejection region for this two-tailed test is R={z:|z|>1.96}

(3) Test Statistics
The z-statistic is computed as follows: 8.708

(4) Decision about the null hypothesis
Since it is observed that |z| = 8.708 > Zc = 1.96, it is then concluded that the null hypothesis is rejected.
Using the P-value approach: The p-value = 0, and since p = 0 < 0.05, it is concluded that the null hypothesis is rejected.

(5) Conclusion
It is concluded that the null hypothesis Ho is rejected. Therefore, there is enough evidence to claim that there is decrease in GRBS after follow up which indicates patients had used medications regularly.

Z – TEST OF SIGNIFICANCE (HbA1c)

PARAMETER 13: Changes in HbA1c by comparing before and after follow up – Z test

HbA1c	Before Follow up	After Follow up
Mean (%)	6.52	5.47
Std. Dev	0.82	0.23

Table 5.13: Changes in HbA1c by comparing before and after follow up – Ztest.

Out of 108 patients the HbA1c levels reduced after the intervention from 6.52±0.82 to 5.47±0.23 which was statistically significant with $p<0.05$

(1) Null and Alternative Hypotheses

The following null and alternative hypotheses need to be tested:

Null

There is no difference in HbA1c level before follow up and after follow up in diabetes patients.

Alternative

There is decrease in HbA1c level after follow up in diabetes, which indicates that patients had used medications regularly.

(2) Rejection Region

Based on the information provided, the significance level is \alpha = 0.05, α=0.05, and the critical value for a two-tailed test is Zc = 1.96.

The rejection region for this two-tailed test is R = {z: |z| > 1.96}

(3) Test Statistics

The z-statistic is computed as follows: 10.82

(4) Decision about the null hypothesis

Since it is observed that |z| = 10.82 > z c = 1.96|, it is then concluded that the null hypothesis is rejected.

Using the P-value approach: The p-value = 0 and since p=0<0.05, it is concluded that the null hypothesis is rejected.

(5) Conclusion

It is concluded that the null hypothesis Ho is rejected. Therefore, there is enough evidence to claim that there is decrease in HbA1c level after follow up which indicates that patients had used medications regularly.

PARAMETER 14.1: Comparison of medication adherence percentage Before and After counselling.

Medication Adherence	Total no of patients N=108	Before Counselling	Total no of patients N=108	After counselling
Low adherence	64	59%	4	4%
Moderate adherence	30	28%	23	21%
High adherence	14	13%	81	75%

Out of 108 patients, 64 patients with (59%) were found to be low adherence, 30 patients with (28%) are moderate adherence and 14 patients with (13%) are high adherence before counselling. After counselling the low adherence reduced to 4 patients with (4%), moderate adherence to 23 patients with (21%) and high adherence shown high improvement among 81 patients with (75%).

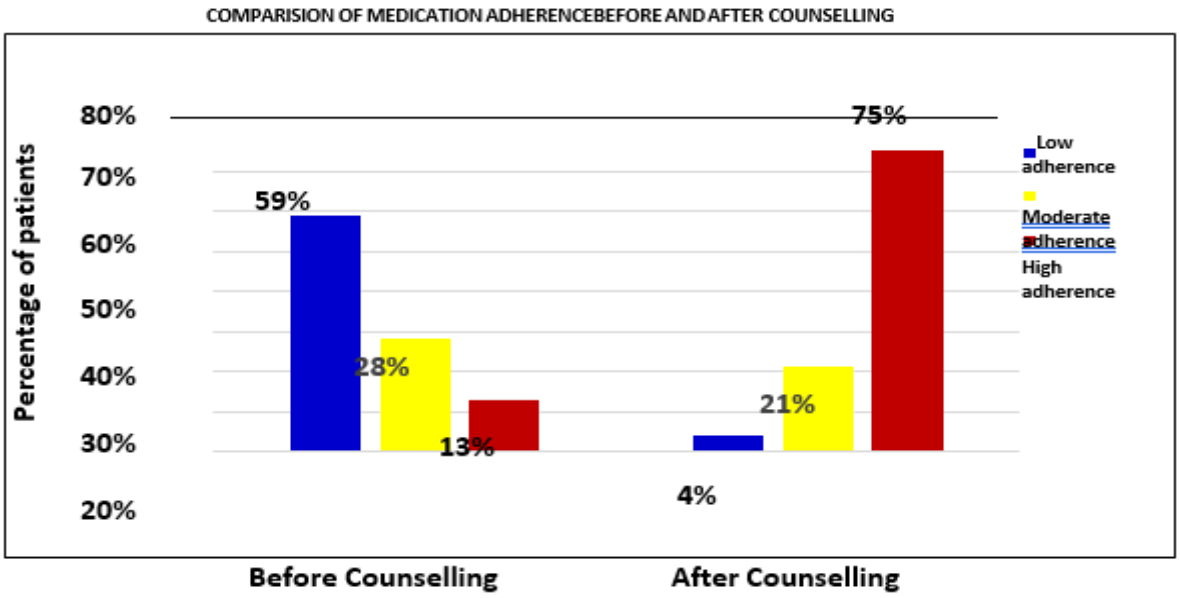


Figure 5.14.1: Comparison of medication adherence Before and After counselling

ANOVA
PARAMETER 14.2:

Table 5.14.2: Impact of clinical pharmacist counselling on medication adherence by comparing medication adherence score before and after

Medication adherence score	Before Follow up	After Follow up
Mean score	3.41	6.21
Std. Dev	1.85	1.10

-up (Before and After counselling)

Out of 108 patients, medication score before follow up is 3.41 and after follow up shows improvement to 6.21. Standard deviation before follow up is 1.85 and after follow up is 1.10.

ANOVA	Degree of Freedom (DF)	Sum of squares	Mean of squares	F Statistic	P value
Groups (Between)	1	423.360	423.60	182.778	0
Error (Within groups)	214	495.678	2.316		
Total:	215	919.037			

ANOVA TABLE

- ANOVA test was applied to assess the difference in medication adherence score in patientswith diabetes before and after follow-up.
- P Value of <0.05 is considered as significant.
- ANOVA test revealed that there exists a statistical significant difference in medication adherence score in patients with diabetes before and after follow-up.
- This study reveals the medication adherence was increased in patients with diabetes after counseling by clinical pharmacists

DISCUSSION

Our study entitled as IMPACT OF CLINICAL PHARMACIST ON IMPROVING MEDICATION ADHERENCE AMONG TYPE-2 DIABETES MELLITUS PATIENTS IN TERTIARY CARE TEACHING HOSPITAL SANGAREDDY: A PROSPECTIVE-INTERVENTIONAL STUDY. A total of 108 patients were enrolled for the study.

GENDER: In relation to parameter 1, out of 108 patients 52 patients 48.14% are males and 56 patients with 51.86% are females which in contrast of the work done by **B.Srijan et.al.,** who c oncluded that out of 260 patients 157 patients with 60.38% were males and 103 patients with 39.61% were females.

AGE: In relation to the parameter 2, out of 108 patients the age group which is high at risk ofdeveloping diabetes mellitus is 41-60 years with 60% patients because age factor plays a major role in treatment which is in accordance with a work done by **John et.al.,** who concluded thatthe age group 41-60 years with 58% patients are at higher risk of developing diabetes mellitus.In our study the data shows that the patients with the age group of 41-60 years are prone to have diabetes than other age groups.

EDUCATIONAL STATUS: In relation to the parameter 3, out of 108 patients 42 patients with 39% were found to be illiterate which in support of work done by **B.Srijan et.al.,** who concluded out of 116 patients 41 patients with 35.34% were found to be illiterate. In our study the data indicates that education is major factor for medication adherence. Awareness and sticking to the medications is most reliable factor for the medication adherence.

SOCIAL HISTORY: In relation to parameter 4, out of 108 patients 42 patients were found to be smoker and 26 patients were found to be alcoholic, 23 patients were found to be both alcoholic, smoker and 17 patients were found to be non-smoker and non-alcoholic which is in accordance with a work done by **Valaparla et.al.,** who concluded that out of 167 patients 38 patients were found to be both smoker and alcoholic, 10 patients were found to be alcoholic, 8 patients were found to be smokers. Based on these findings our study concludes that both smoking and consumption of alcohol are risk factors for development of cardiac complicationsin type-2 diabetes patients.

COMPLICATIONS: Occurrence of complications are most common among diabetic patients who are non-adherent to medications and life style modification. In relation to parameter 5, out of 108 patient's multiple complications were observed in patients with diabetes mellitus among that 93% of the study population reported microvascular complications which is almost similar to study conducted by **Valaparla et.al.,** who concludedthat 82% of the study population reported microvascular complications.
Table.5.11 shows relation between diabetes and occurrence of the complications in diabetes patients with respect to gender. Neuropathy was the common complication was observed in most of the diabetes patients. Chi-square test was applied and revealed that there exists no statistical significant relation between Diabetes and occurrence of complications in diabetes patients with respect to gender.
Based on these findings it is observed that majority of type-2 diabetic patients are non-adherent to prescribed medications and life-style modifications which increases the chance of early onset time of complications which effects the individual quality of life, hospitalization, increased mortality and decreased rate of life expectancy. Adherence to medications and life style modification could delay the onset of complications and improves the quality of life.

COMORBIDITIES: In relation to parameter 6, out of 108 patients 60% of the patients were found to be hypertensive, obesity 14%, chronic renal failure 7%, hyperlipidemia 5%, chronic heart disease 4%, cerebrovascular accident 1% and is in contrast with work done by **Manju.at.el.,** who concluded that regarding the diabetes associated comorbidities, hypertension was found in majority of patients 57.8% patients , hyperlipidemia 28.9%,coronary artery disease 23.9%, cerebrovascular accident 4.6%.
Table 5.10: shows Relation between comorbid condition and occurrence of diabetes with respect to gender. Hypertension was the common comorbid condition observed in most of the Diabetes patients. Chi-Square test revealed that there exists no statistical significant relation between comorbid condition and occurrence of the Diabetes with respect to gender.

The medication knowledge should be improved mostly in patients with comorbidities. The importance of regular follow up of diabetic patients with the health care provider is of great significance in averting any long-term comorbidities.

DURATION OF DIABETES: In relation to parameter 7, Out of 108 patients, 26 patientswith (24%) had been diagnosed with diabetes for the past 1-5 years, 48 patients with (44%) had been diagnosed with diabetes for the past 5-10 years followed by 34 patients with (32%) had been diagnosed with diabetes for the past more than 10 years which is in contrast to the work done by **Judith Basker et.al.,** who concluded that majority of the study population had been diagnosed with diabetes for the past 1-5 years(48.75%) followed by 6-10 years (27.75%).

ANTI DIABETIC THERAPY: In relation to the parameter 8, Out of 108 patients, 66 diabetic patients with (61%) were prescribed with one anti diabetic drug, 42 diabetic patients with (39%) were using combination therapy which is in contrast with the work done by **JudithBasker et.al.,** who concluded that 70 % of the diabetic patients were prescribed with just one anti diabetic agent, about 26 % of the patients were using a combination of two drugs.

FACTORS ASSOCIATED WITH MEDICATION NON-ADHERENCE: *In* relation to the parameter 9, Forgetfulness, Poor follow up, Decrease in symptom severity, Polypharmacy, Low health literacy, Busy schedule, Poor communication between provider and patient, Depression and Duration of therapy were the most frequent reasons given by the participants as the reasons for their non-adherence to medication. These findings are in accordance to the study conducted by **Jackson et.al.,** who concluded that factors affecting themedication non-adherence are forgetfulness, low health literacy, poor patient provider communication and depression.

In present study lack of awareness to medication was another reason for the treatment interruption which is due to the forgetfulness to take the medicines on time which is in agreement to the study done was **Agrawal N et.al.,** who concluded that non- adherence was more related to the patient forgetfulness. The similar study was conducted **Aminde et.al.,** whoconcluded that forgetfulness was the main reason for medication non-adherence. To address patient forgetfulness there is need for regular follow up and it can be effectively overcome by helping diabetic patients remembering to take their medications by setting alarms in accordance to their medication time to improve adherence to medication, improve glycemic control over all health outcomes.

This study is in agreement with the earlier studies that identified patient provider- communication as a major determinant of the adherence behavior. The health care provider should have a patient centered approach, establish and maintain a rapport and communicate clearly with patients. A part from the physician, the patient also has important role to play in the communication with the health care provider, particularly during the clinical encounter.

Depression is a common among the patients with diabetes and has implications for their quality of life, medication adherence, health care cost. Because an individual own psychological statecan influence the self-efficacy judgements regarding specific task, patient who are depressive tend to have poor diabetes self-care and feel that they have less control over their disease. In the present study some of the patient's reported depression is one of the reasons for their non adherence to medication. Patient education as well as psychological treatment of depressed patients will be enormously helpful in medication adherence and diabetes self-care.

GRBS: In relation to parameter 12, out of 108 patients the GRBS level reduced after the intervention from 241±103.2 to 160±38 which was statistically significant with p<0.05 whichin contrast to the work done by **Manju et.al.,** who concluded that the GRBS level has been reduced after the intervention from 202±82.56 to 170±52.93 which was statistically significantwith p<0.05.

HbA1c: In relation to parameter 13, out of 108 patients the HbA1c levels reduced after the intervention from 6.52±0.82 to 5.47±0.23 which was statistically significant with p<0.05 whichin contrast to the work done by **Chaudhary et.al.,** who concluded that HbA1c levels reduced from 8.46±1.32 to 7.78±1.64 which was statistically significant with p<0.05.

OUTCOME OF THE GLYCEMIC LEVELS: Statistically significant improvements (p<0.05) in the blood glucose level of both GRBs and HbA1c levels were observed in before follow up and after follow up until the end of the study period. The studiesshows that pharmacist education, follow up calls proved beneficial in reducing the mean blood glucose significantly. These findings are similar to the **Shareef et.al.,** study which show that the pharmacist led patient education and medication counselling was effective in improving medication adherence and glycemic levels in patients with type-2 diabetes mellitus patients.

MEDICATION ADHERENCE: In relation to the parameter 14**,** A total of 108 patient's, low-adherence has been reduced from 59% to 4%, moderate-adherence percentage reduced from 28% to 21% and high adherence percentage rose from 13% to 75% after the pharmacist intervention which in accordance of **Manju et.al.,** who concluded that poor adherence has been reduced from 48.2% to 26.1%, moderate adherence percentage rose from 32.1% to 31.1% after the pharmacist intervention.

In relation to the parameter 14.2, Out of 108 patients, mean medication score before follow upis 3.41 and after follow up shows improvement to 6.21. Standard deviation before follow up is 1.85 and after follow up is 1.10.

A statistical ANOVA test was applied to assess the difference in medication adherence score in patients with diabetes before and after follow up. ANOVA test revealed that there exist a statistically significant difference in medication adherence score in patients with diabetes before and after follow up. The p value =0 (<0.005) which is statistically significant. This study reveals the medication adherence was increased in patients with diabetes after the clinicalpharmacist intervention.

4. CONCLUSION

Age group of 41-80 years were more prone to Diabetes Mellitus which may be due to insulin resistance, Islet cell dysfunction and abnormal glucose metabolism has associated with aging.

Multiple complications were observed in patients with diabetes mellitus among that, Microvascular complications are more common. Complications usually occurs in a patient's who are non -adherent to medications and life style modifications. We have counselled the patient's regarding the importance of medication adherence, life style modifications to delay early onset of complications and to improve the quality of life.

Individuals with chronic asymptomatic diseases are do not adhere to treatment frequently, since the absence of symptoms lower their motivation to take their drugs continuously. In addition, the existence of other comorbid conditions that are treated with various medications(i.e., Polypharmacy) is also one of the major factors that contribute to non- adherence. Hypertension was the common comorbid condition observed in most of the Diabetes patients. We as a clinical pharmacist maintained a good relationship with the patient to provide psychological support, giving the individual the basic skills to adhere to medication and developing the beliefs on the benefits of therapy.

Forgetfulness, decrease in symptom severity, polypharmacy, low health literacy, busy schedule, poor communication between provider and patient, depression and duration of therapy were the most frequent reasons given by the participants as the reasons for their non- adherence to medication. To avoid these barriers and to improve adherence educational interventional is needed. So, we did an educational intervention by counselling the patients about medications and their indications.

A Significant improvement in GRBS and HbA1c was observed during the study by the clinicalpharmacist intervention. We as a clinical pharmacist provided a patient counselling on disease,medication, diet and life style modifications. It was achieved through a personal face-to-face interaction, supply of patient information leaflet and telephonic follow up. This has created an awareness of the patient not only in appropriate use of medication but also the life style modifications.

The study concluded that pharmacist intervention had a significant impact in improving the disease, medication adherence, overall quality of life by effectively monitoring the patient.

Further research is needed to improve medication adherence and to prevent the factors associated with medication non adherence.

Impact of clinical pharmacist on improving medication adherence among Type- 2 Diabetes mellitus patients in Tertiary care teaching Hospital, Sangareddy: A Prospective- Interventional study.

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