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Evaluate the Efficacy of Metformin and Glimepiride with Metformin in Patients with Type II Diabetes Mellitus

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Abstract: ***Introduction: Diabetes mellitus is a group of metabolic disorders characterized by hyperglycemia. The hyperglycemia results from defects in insulin secretion, insulin action or both. The chronic hyperglycemia of diabetes is associated with specific chronic complications resulting in damage to or failure of various organs, notably the eyes, kidneys, nerves, heart and blood vessels. Aims and Objectives of the Study: To evaluate the efficacy of Metformin and Glimepiride with Metformin in patients with type II DM. Methodology: Materials: Patient prescription form, Case history form, Blood Glucose levels. Methods: The study was conducted over a period of six months. Sample size is 150 patients. Study conducted at Shree Shakthi Nursing Home, Yemmiganur. All Individuals eligible for participation were men and women between the ages of 45-85 years with type II Diabetes Mellitus by American Diabetes Association criteria who were diagnosed with type II DM. Exclusion criteria include pregnancy people and patients with coronary artery diseases. Discussion: The study was carried for a period of six months at Sri Shakhti Nursing Home, Yemmiganur. Based on inclusion and exclusion criteria a total of 150 subjects were included. 54 subjects were on monotherapy, 96 subjects were on dual therapy. Conclusion: In newly detected type II DM, Metformin alone is started along with lifestyle modifications. Good glycemic controls were achieved for patients whose sugar levels are not under controlled with metformin or for long standing diabetes patients dual therapy of metformin with glimipiride was started. Significant number of patients achieved good glycemic control.***

Keywords: Better Treatment Pattern in Type II Diabetes Mellitus

1. Introduction

Diabetes mellitus is a group of metabolic disorders characterized by hyperglycemia. The hyperglycemia results from defects in insulin secretion, insulin action or both. The chronic hyperglycemia of diabetes is associated with specific chronic complications resulting in damage to or failure of various organs, notably the eyes, kidneys, nerves, heart and blood vessels.

2. Classification

Type I Diabetes
This form of diabetes results from autoimmune destruction of the β cells of the pancreas. Markers of immune destruction of the βcell are present at the time of diagnosis in 90% of individuals and include islet cell antibodies, antibodies to glutamic acid decarboxylase, and antibodies to insulin. Although this form of diabetes usually occurs in children and adolescents, it can occur at any age. Younger individuals typically have a rapid rate of β -cell destruction and present with ketoacidosis, whereas adults often maintain sufficient insulin secretion to prevent ketoacidosis for many years, which is often referred to as LADA.[2]

Type II Diabetes
This form of diabetes is characterized by insulin resistance and a relative lack of insulin secretion, with progressively lower insulin secretion over time. Most individuals with type II diabetes exhibit abdominal obesity, which itself causes insulin resistance. In addition, hypertension, dyslipidemia (high triglyceride levels and low HDL-cholesterol levels), and elevated plasminogen activator inhibitor type I (PAI-I) levels are often present in these individuals. This clustering of abnormalities is referred to as the insulin resistance syndrome or the metabolic syndrome. Because of these abnormalities, patients with type II diabetes are at increased risk of developing macro vascular complications. Type II diabetes has a strong genetic predisposition and is more common in all ethnic groups other than those of European ancestry. At this point the genetic cause of most cases of type II diabetes is not well defined.[3]

Gestational Diabetes Mellitus
GDM is defined as glucose intolerance that is first recognized during pregnancy. Gestational diabetes complicates approximately 7% of all pregnancies. Clinical detection is important, as therapy will reduce perinatal morbidity and mortality.[3]

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WHO criteria for the diagnosis of diabetes are:

- Fasting plasma glucose >7.0 mmol/L (126 mg/dL)
- Random plasma glucose >11.1 mmol/L (200 mg/dL)
- One abnormal laboratory value is diagnostic in symptomatic individuals; two values are needed in asymptomatic people.

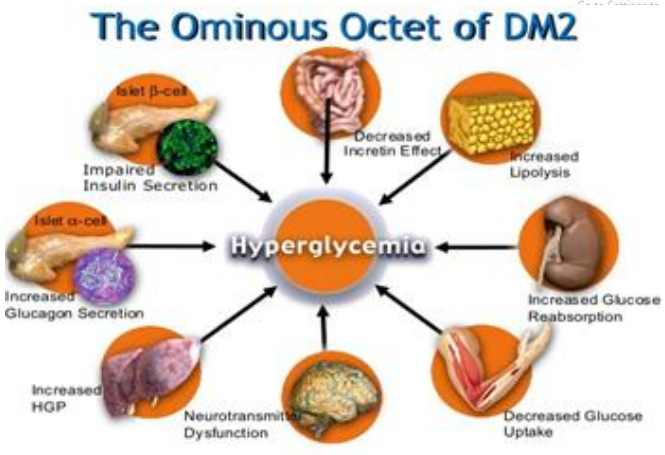
The glucose tolerance test is only required for borderline cases and for diagnosis of gestational diabetes.

The glucose tolerance test – WHO criteria

	Normal	Impaired glucose tolerance	Diabetes mellitus
Fasting	<7.0 mmol/L	<7.0 mmol/L	>7.0 mmol/L
2 h after glucose	<7.8 mmol/L	7.8–11.0 mmol/L	≥11.1 mmol/L

- Adult: 75 g glucose in 300 mL water
- Child: 1.75 g glucose/kg body weight
- Only a fasting and a 120-min sample are needed
- Results are for venous plasma – whole blood values are lower.

Note: There is no such thing as mild diabetes. All patients who meet the criteria for diabetes are liable to disabling long-term complications.



Epidemiology

The prevalence of type II DM is increasing. Type II DM accounts for as much as 90% of all cases of DM, and the overall the prevalence of type II DM in the United States is approximately 9.6% in persons' age 20 years or older. However, there is likely one person undiagnosed for every three persons currently diagnosed with the disease.[4]

Multiple risk factors for the development of type II DM have been identified, including family history (i.e., parents or siblings with diabetes), obesity (i.e., ≥20% over ideal body weight, or body mass index [BMI] ≥25 kg/m^2).

Aims and objectives of the study

To evaluate the efficacy of Metformin and Glimepiride with Metformin in patients with type II DM.

3. Methodology

Materials

- Patient prescription form
- Case history form
- Blood Glucose levels

Methods

Study period

The study was conducted over a period of six months.

Sample size

Sample size is 150 patients.

Study Site

Shree Shakthi Nursing Home, Yemmiganur.

Study criteria

Inclusion criteria

All Individuals eligible for participation were men and women between the ages of 45-85 years with type II Diabetes Mellitus by American Diabetes Association criteria who were diagnosed with type II DM.

Exclusion criteria

Exclusion criteria include pregnancy people and patients with coronary artery diseases.

Ethical clearance

Institutional review board has accepted this project.

Statistical methods

Statistical analysis done by using Microsoft Office Excel 2007.

Chi square test: This is used to compare two or more mutually exclusive proportion. This is most widely used statistical test. This is a Non parametric test.

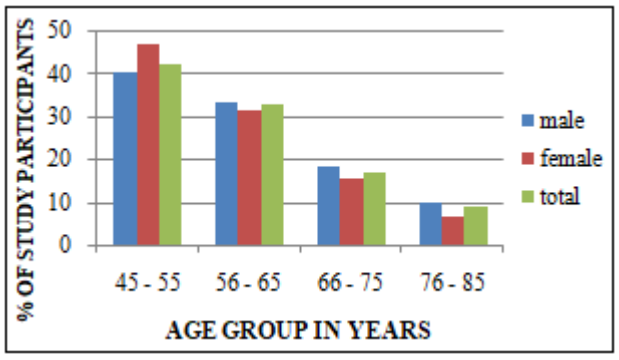
Figures and Tables

4. Discussion

The study was carried for a period of six months at Sri Shakhti Nursing Home, Yemmiganur. Based on inclusion and exclusion criteria a total of 150 subjects were included. 54 subjects were on monotherapy, 96 subjects were on dual therapy.

Diabetes mellitus, mainly the type 2 form, is a major public health issue globally and affected about 347 million individuals worldwide in 2008 almost 10% of adults. When metformin alone is insufficient, the choice of second-line treatment is challenging and there is no clear consensus on the optimum approach, although algorithms provide some guidance.

It is well known that the risk of type II DM increases as the age advances In this study maximum numbers of study subjects were seen in the age group of45-55 years in both male (40%) and female (46.6%) study subjects. shows that number of study subjects seen in the age group of 45-55 years (42%), 56-65 years (32.7%), 66-75 years (16.7%), and 76-85 years (8.7%).



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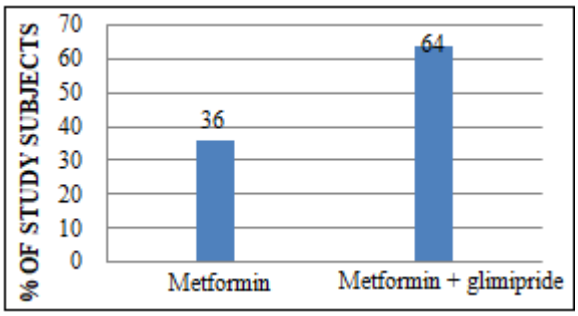
Out of 150 subjects 36% of study subjects were using monotherapy (Metformin) followed by 64% of study subjects on dual therapy (Glimipride+Metformin) This study showed comparative data of monotherapy and dual therapy.

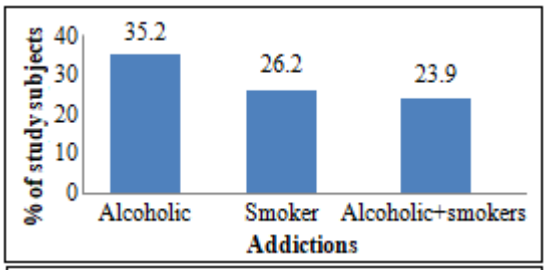
In this study concluded that 61.1% of study subjects were controlled on monotherapy followed by 89.6% of study subjects were controlled on dual therapy. 38.9% of study subjects were uncontrolled on monotherapy followed by 10.4% of study subjects were uncontrolled on dual therapy.

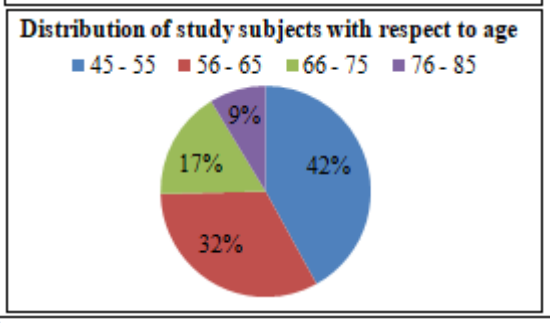
Though in our study dual therapy is statistically significant (1.04< 5) in controlling sugars, good number of patients had glycemic control.

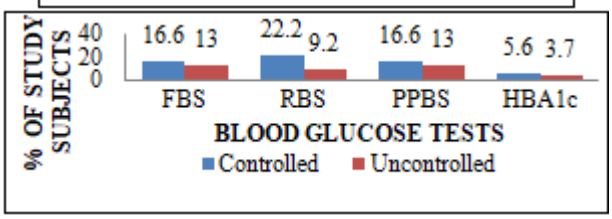


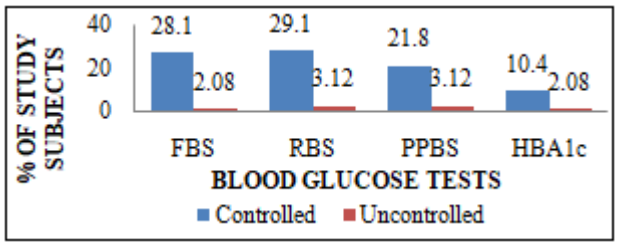
Distribution of smoking habit and alcohol consumption

In this study out of 150 subjects 37.3% were consuming alcohol and 32.7% of study subjects were smokers (Table 3 and Fig.6.8). In this study we demonstrated that moderate to heavy alcohol consumption was associated with higher blood glucose levels and very light alcohol consumption was associated with reduced blood glucose levels.

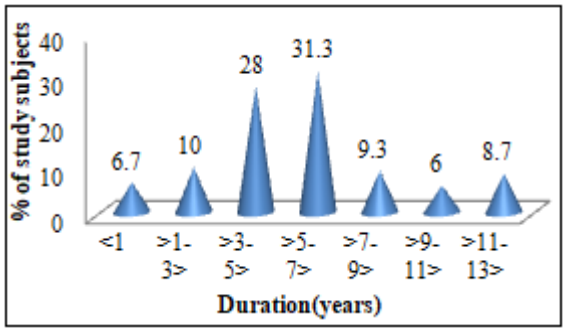






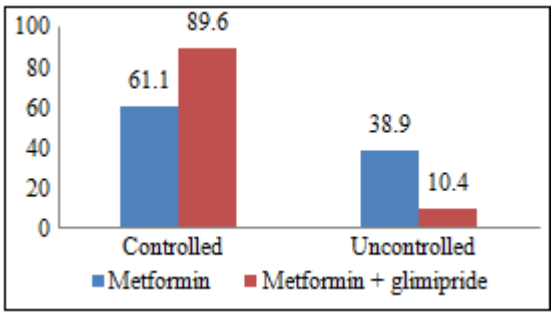


METFORMIN+GLIMIPRIDE	
No. of patients	Percentage (%)
86	89.6
10	10.4



Correlation of blood glucose tests with respect to Dual therapy

In this study, we measured the blood glucose levels. Out of 150 study subjects, 54 were on Monotherapy. Patients whose blood sugar levels were not controlled on Monotherapy were shifted to Dual therapy .In that (Table 6 and Fig.6.11) concluded that 28.1% (27) of subjects was achieved the normal FBS levels followed by 2.08%(2) were comes under uncontrolled group. 29.1% (28) of subjects was achieved the normal RBS levels followed by 3.12% (3) were comes under uncontrolled group. 21.8% (21) of study subjects was achieved they were normal PPBS levels followed by 3.12%.In this study the percentage of patients with an controlled HbA1c is 10.4% (10) followed by 2.08%(2) comes under uncontrolled group.



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5. Equations

$$\chi_c^2 = \sum \frac{(O_i - E_i)^2}{E_i}$$

6. Recommendations

Based on the findings of this study, it is recommended that, there is need of further studies to be performed at regular

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intervals in accordance to evaluate the efficacy of oral hypoglycemic produced which may be beneficial in the management of Type II DM.

7. Conclusion

In newly detected type II DM, Metformin alone is started along with lifestyle modifications. Good glycemic controls were achieved for patients whose sugar levels are not under controlled with metformin or for long standing diabetes patients dual therapy of metformin with glimipiride was started. Significant number of patients achieved good glycemic control.

Although both treatments were generally well tolerated, glimepiride with metformin combination had a considerably more efficacy. Hence this study concluded that Dual therapy(Glimepiride+Metformin) is more effective when compared to monotherapy(Metformin) helps in treating the type II DM.

Though dual therapy has better efficacy than metformin alone. Every patient has to have individualized treatment approach.

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