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Effectiveness of Oral Hypoglycaemics in Type-2 Diabetes Mellitus Patients at a Tertiary Care Hospital : A Comparative Observational Study

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ABSTRACT

Hyperglycemia, or a state of high blood sugar, is a symptom of diabetes mellitus (D.M.), a complicated chronic disease brought on by deficits in insulin production, activity, or both. Since type 2 diabetes mellitus is a frequent and spreading condition, it is a significant global public health issue. The International Diabetes Federation estimates that 629 million people will have diabetes by 2045, up from the current 425 million cases. The main objective is to compare the effectiveness of oral hypoglycaemics in Type-2 Diabetes Mellitus patients at a tertiary care hospital. This prospective observational study was carry out for six months at HKES's Basaveshwar Teaching and General Hospital, Kalaburagi. Patients were enrolled based on eligibility criteria. Study populations of 120 subjects with incident Type 2 Diabetes Mellitus were enrolled. Among 120 issues, 25 (20.83%), 15 (12.5%), and 20 (16.66%) subjects are under the treatment of Biguanides, Sulfonylureas, and DPP-4 Inhibitors. 10 (8.33%), 30 (25%) and 20 (16.66%) subjects are under the treatment of Biguanides and Sulfonylureas combination, Biguanides and DPP-4 Inhibitors combination and Biguanides, Sulfonylureas and DPP-4 Inhibitors combination. Finally, conclude that the DPP4 Inhibitor combination group of drugs is better than other anti-diabetic medications in maintaining good glycemic status in type 2 D.M. patients, particularly Biguanides+DPP-4 Inhibitors and then followed by Biguanides+DPP-4 Inhibitors + Sulfonylureas by comparing all the laboratory values obtained.

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INTRODUCTION

Hyperglycemia, or a state of high blood sugar, is a symptom of diabetes mellitus (D.M.), a complicated chronic disease brought on by deficits in insulin production, activity, or both. Patients are at significant risk for long-term macro- and microvascular consequences due to the chronic metabolic imbalance associated with this condition, which can result in recurrent hospitalizations and sequelae, including an increased risk for cardiovascular diseases (CVDs) [1].

The four plasma glucose (P.G.) criteria are: increased I fasting plasma glucose (F.P.G.) (>126 mg/dl), (ii) 2-hour P.G. during a 75-g oral glucose tolerance test (OGTT) (>200 mg/dl), (iii) random P.G. (>200 mg/dl) with characteristic signs and symptoms of hyperglycemia, or (iv) Hemoglobin A1C level >6.5 percent. The American Diabetes Association (A.D.A.) recently recommended against favoring one test over another for diagnosis. Regardless of body weight, it is advised to test all

people starting at age 45. Asymptomatic individuals who are overweight or obese, appear with a diagnostic symptom, and have at least one additional risk factor for developing diabetes should also be tested. Additionally, pre-diabetes, also known as impaired fasting glucose (I.F.G.), predisposes patients to diabetes, insulin resistance, and a higher risk of cardiovascular (CV) and neurological pathologies [2, 3]. In this condition, the fasting blood glucose is elevated above average but does not reach the threshold to be considered diabetes (110-126 mg/dl).

Type 2 diabetes mellitus (T2DM) can co-occur with other illnesses, including pancreatic disease linked to cystic fibrosis or gestational diabetes that manifests during the second or third trimester of pregnancy. T2DM can also be caused by medical interventions, such as using glucocorticoids in a hospital context or administering potent antiretrovirals to HIV-positive patients, such as protease inhibitors and nucleoside reverse transcriptase inhibitors [4]. Thiazide diuretics, atypical antipsychotic medications, and statins can all cause chemical diabetes or impaired glucose tolerance (I.G.T.) [5, 6]. Since type 2 diabetes mellitus is a frequent and spreading condition, it is a significant global public health issue. According to the International Diabetes Federation, 387 million individuals worldwide have been diagnosed with diabetes [7].

Diabetes was diagnosed in 29.1 million individuals in the United States in 2012, or 9.3 percent of the population, according to the Centers for Disease Control and Prevention (US). 86 million people had pre-diabetes in the same year, and 15 to 30 percent progressed to full-blown diabetes [8]. Generally speaking, 1.4 million newly diagnosed cases are recorded in the U.S. each year. One in three Americans will have diabetes in 2050, according to projections, if this trend keeps up. Diabetes patients are more likely to have significant health issues such as myocardial infarction, stroke, renal failure, eyesight loss, and early death. The seventh most important cause of death in the U.S. is still diabetes and its related side effects. If conscious attention is not given, the World Health Organization predicts that the number of deaths attributable to diabetes will quadruple by 2030 [9]. Additionally, epidemiological studies reveal that diabetes kills more Americans annually than breast cancer and AIDS [10].

The alarming rise in diabetes incidence and prevalence places a heavy load on our present healthcare system and medical bills. To enhance diabetes outcomes, the A.D.A. has published a set of guidelines called Standards of Medical Care in Diabetes. The suggestions include low-cost screening, diagnostic, and treatment methods to stop, postpone, or successfully manage T2DM and its potentially fatal consequences [11]. Diabetic ketoacidosis (DKA) is a severe consequence that can occasionally affect T2DM patients [12].

According to the A.D.A. and other organizations' guidelines, contemporary methods of treating diabetes should entail a multidisciplinary team of medical specialists cooperating with the patient and their family. These strategies' main goal is to achieve optimal glycemic control through dietary and lifestyle changes, using the right medicines, and monitoring blood glucose. If patients' compliance and involvement are clinically applied, together with the standard of treatment, the burden of diabetes will be. Both types of diabetes affect people of all ages. Therefore the conventional presentations that type 2 diabetes (T2DM) exclusively affects adults and type 1 diabetes (T1DM) only affects children are inaccurate. As the plethora of oral hypoglycemics available in the market to treat type 2 diabetes, it is essential to know which drugs are more effectively working. So, there is a need to carry out the present study. Aim to study the effectiveness of oral hypoglycaemics in type-2 Diabetes Mellitus patients. Objectives to find which drug is more effective than other anti-diabetic medication to maintain good glycemic status in type 2 D.M. To find whether the drug is effective or a combination of drugs would be effective.

METHODOLOGY

Place of the Study

This study is carried out at HKES's Basaveshwar Teaching and General Hospital, Kalaburagi.

Period of the Study

The study is carried out for six months.

Study Design

Comparative observational study.

Study Population

120.

Patient Enrollment

Inclusion Criteria

1. Male and female patients having type 2 diabetes.

2. Patients of age ≥ 35.

3. Patients with regular follow up for six months.

4. Patients who are willing to give consent.

Exclusion Criteria

1. Age below 35 years.

2. Pregnancy and lactating mothers.

3. Patients with other co-morbid diseases.

4. Patients with irregular follow up.

5. Type 1 diabetes and gestational diabetes patients.

6. Patients who are not willing to give consent.

Study Materials

1. Patient data collection and questionnaire form

2. Informed consent form

Method of Study

1. Patients were enrolled based on eligibility criteria.

2. Data is collected according to the data collection form.

3. Using a questionnaire form, all the information required to be collected.

4. A total of three follow up were done.

5. Baseline laboratory information was collected.

6. For each follow-up, the drug efficacy was compared based on the glucose levels.

7. Counseling on diet control was given at each follow-up.

8. At the third follow-up, each drug's effectiveness was illustrated, and results were reported.

Statistical Analysis

1. The required information was collected and tabulated, and the frequencies and percentages were calculated wherever needed.

2. Paired t-test was conducted between the Age group, Gender, Risk factors, Vs. Elevation of glucose levels to find the clinical association between them.

RESULTS

A study population of 120 subjects with incident Type 2 Diabetes Mellitus was enrolled. Out of these 120 subjects, 15 issues are under the age group of 36-45 years, which comprises 12.5%; 25,30,20 and 30 topics are under the age group of 46-55, 56-65, 66-75, $\geq$76 years, respectively, which contains 20.83%, 25%, 16.66% and 25% of study population respectively. The distribution of Type-2 diabetes subjects based on gender is given in Figure 1.
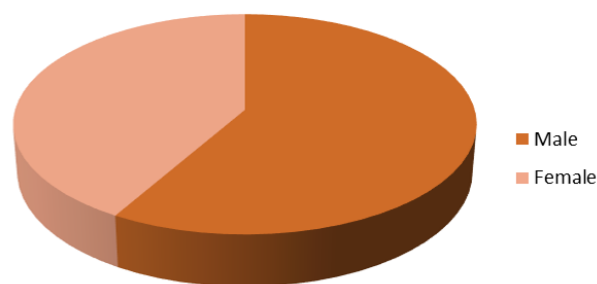

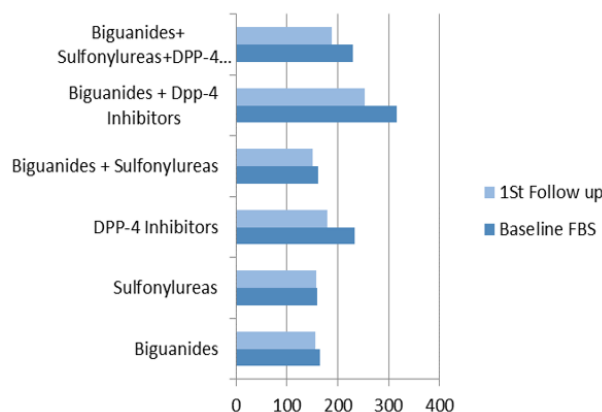**Figure 1: Distribution of Type-2 Diabetes Subjects Based on Gender**

Figure 2: Change in F.B.S. Levels From Baseline Among the Subjects

Change in F.B.S. levels from baseline among the Subjects to 1st follow-up, 2nd follow-up & 3rd follow-up was represented in Figure 2, Figure 3 & Figure 4, respectively. Among 120 subjects 25, 15 and 20 subjects are under the treatment of Biguanides, Sulfonylureas and DPP-4 Inhibitors which comprises about 20.83%, 12.5% and 16.66% of the study population. 10, 30 and 20 subjects are under the treatment of Biguanides and Sulfonylureas combination, Biguanides and DPP-4 Inhibitors combination and Biguanides, Sulfonylureas and DPP-4 Inhibitors combination, which comprises about 8.33%, 25 and

Table 1: Incidence of Risk Factors Among the Subjects

S. No	Risk factors	No. of Subjects
1.	Genetic factors	22
2.	Obesity	20
3.	Smoking/alcohol consumption	12
4.	Genetic factors & Obesity	10
5.	Smoking and alcohol consumption & Obesity	15
6.	Genetic factors & Smoking/alcohol consumption	18
7.	Genetic factors, Smoking/alcohol consumption & Obesity	23

Table 2: Conducting Paired T-Test Between Age Group, Gender, Risk Factors Vs. Elevation of Glucose Levels

S. No	Characteristics	P-Value
1.	Age group 36-45 years 46-55 years 56-65 years* 66-75 years* $\geq$76 years*	*P<0.05
2.	Gender Male* Female	*P<0.05
3.	Risk factors Genetic factors* Obesity* Smoking and alcohol consumption* Genetic factors & Obesity* Smoking and alcohol consumption & Obesity* Genetic factors & Smoking/alcohol consumption* Genetic factors, Smoking/alcohol consumption & Obesity*	*P<0.05

*P<0.05: There is a robust clinical association with an elevation of glucose levels
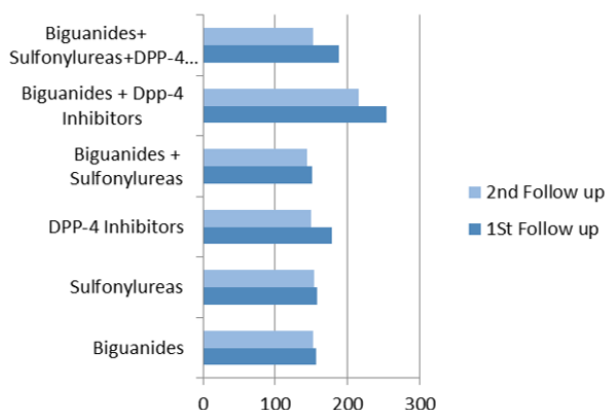
Figure 3: Change in F.B.S. Levels After 1st Follow-Up Among the Subjects
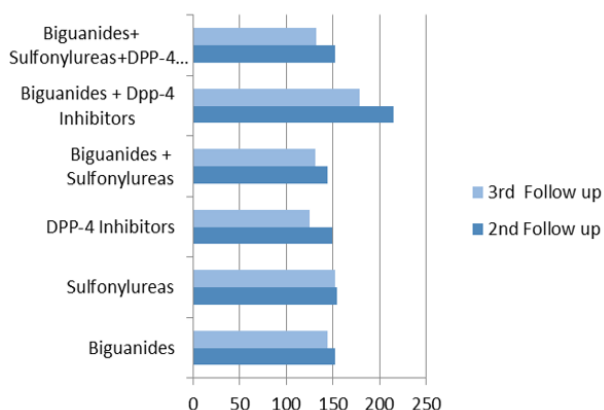

Figure 4: Change in F.B.S. Levels After 2nd Follow-Up Among the Subjects

16.66% of the study population.

Change in HbA1c levels from baseline among the subjects to 1st follow-up, 2nd follow-up & 3rd follow-up was represented in Figure 5, Figure 6 & Figure 7, respectively. Change in PPBS levels from baseline among the subjects to 1st follow-up, 2nd follow-up &
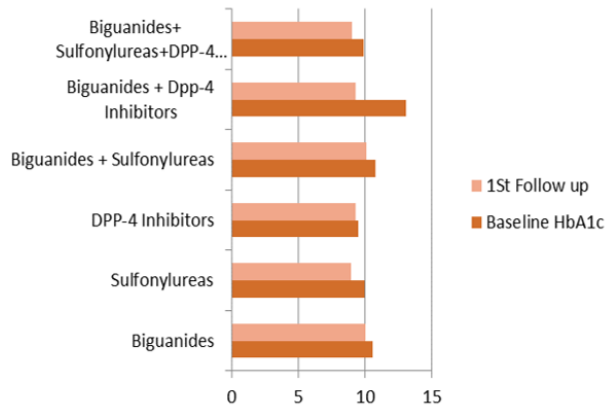
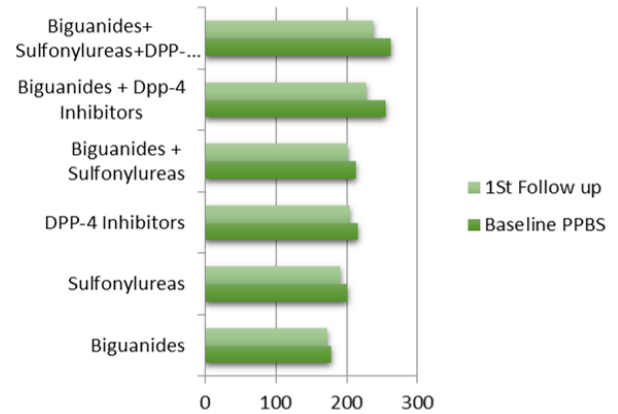**Figure 5: Change in HbA1c Levels from Baseline Among the Subjects**

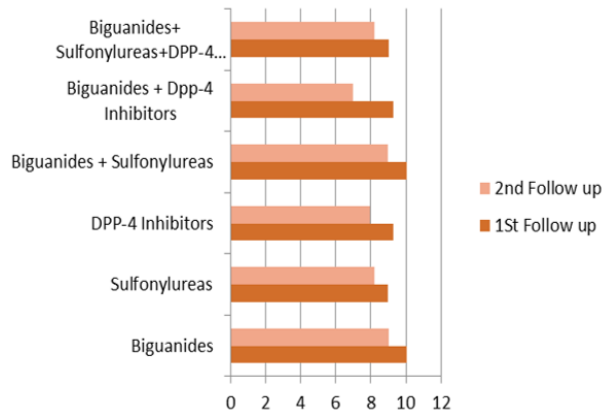**Figure 8: Change in PPBS Levels from Baseline Among the Subjects**

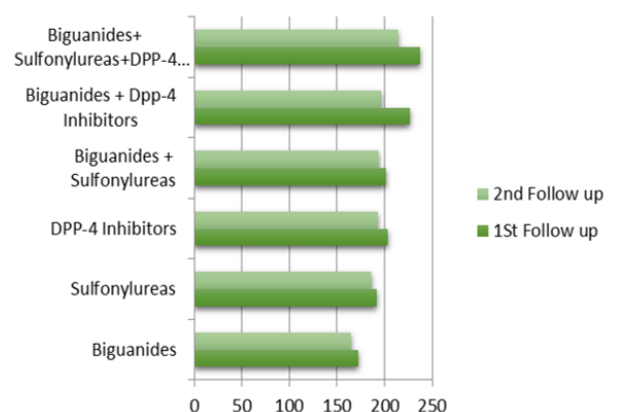**Figure 6: Change in HbA1c Levels After 1st Follow-Up Among Subjects**

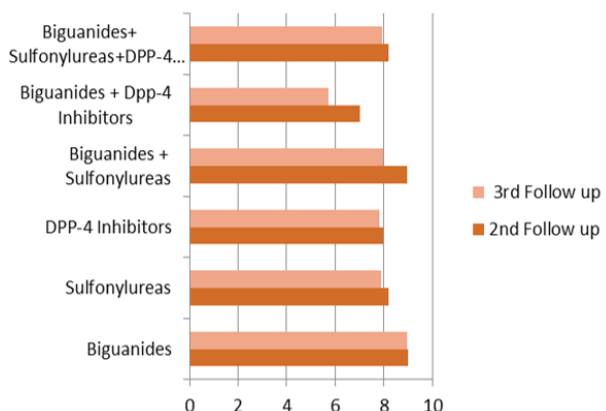**Figure 9: Change in PPBS Levels After 1st Follow-Up Among the Subjects**

Figure 7: Change in HbA1c Levels After 2nd Follow-Up Among Subjects
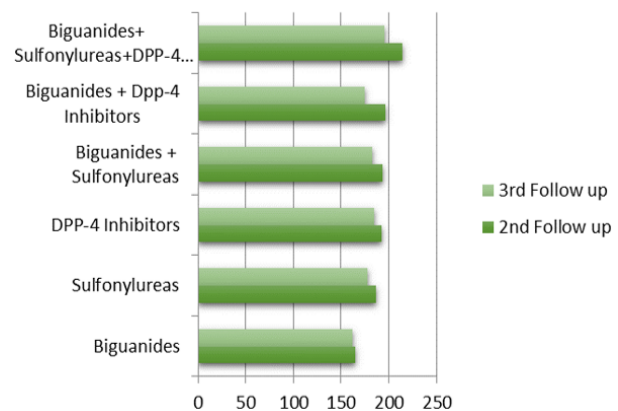

Figure 10: Change in PPBS Levels After 2nd Follow-Up Among the Subjects

3rd follow-up was represented in Figure 8, Figure 9 & Figure 10, respectively.

Results were obtained by Conducting Paired t-tests between Age group, Gender, Risk factors Vs. The incidence of Risk factors among the subjects was tabulated in Table 1. The elevation of glucose levels is given in Table 2.

DISCUSSION

As per statistical analysis, there was a solid clinical association between the age group and Type-2 DM. Based on age-wise categorization, 56-65 years, 66-75 years, and ≥76 years* age group patients are more prone to Type-2 DM than other age groups. Based on gender-wise categorization, males are more prone to Type-2 DM than females. Biguanides and DPP-4 Inhibitors combination drugs are more prescribed than other drugs [13].

Change in F.B.S. levels from baseline to 1" follow-up was highest with BG DPP-4 Inhibitors [13]. Changes in F.B.S. levels from 1st to 2nd follow-up were highest with BG+DPP-4 Inhibitors. Our study was supported by Ou SM, Shih CJ, et al. studies [14]. Change in F.B.S. levels from 2nd to 3rd follow-up was highest with BG+DPP-4 Inhibitors [13]. Change in HbA1c levels from baseline to 1st follow-up was highest with BG+DPP-4 Inhibitors. Our study was supported by Charpentier et al. studies [14]. Change in HbA1c levels 1st to 2nd follow-up was highest with BG+DPP-4 Inhibitors [13]. Change in HbA1c levels from 2nd to 3rd follow-up was highest with BG+DPP-4 Inhibitors [14]. Change in PPBS levels from baseline to 1st follow-up was highest with BG+DPP-4 Inhibitors [13]. Change in PPBS levels and BG+DPP-4 Inhibitors ($p>0.05$, by using Paired t-test). Change in PPBS levels from 1 to 2nd follow-up was highest with BG+DPP-4 Inhibitors [14]. Change in PPBS levels from 2nd to 3rd follow-up was highest with BG+DPP 4 Inhibitors. Our study was supported by Ou SM, Shih CJ, et al. studies" [13]. Obesity and genetic factors were the significant risk factor for Type-2 DM when compared to other risk factors. As per statistical analysis, there was a solid clinical association between obesity and Type-2 DM [15].

CONCLUSION

One of the chronic conditions is diabetes. Based on the patient's features, the degree of hyperglycemia, and the available treatment choices, type 2 diabetes is treated. Our understanding and capacity to control diabetes are quickly developing due to the mounting evidence for novel technology and therapeutic strategies. Among the oral drugs used worldwide, metformin, sulfonylureas (S.U.), and DPP IV inhibitor are the most researched. They have a significant initial part in the treatment algorithm for type 2 diabetes that was suggested by several guidelines. Choosing the right anti-diabetic medicine and maintaining reasonable glycemic control is essential for managing D.M. This study found that Biguanides+DPP-4 Inhibitors and Biguanides+DPP-4 Inhibitors + Sulfonylureas were the two anti-diabetic drug combinations that were most effective in maintaining excellent glycemic control in type 2 D.M. patients.

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