Frontiers in Health Informatics
ISSN-Online: 2676-7104
www.healthinformaticsjournal.com
2024; Vol 13: Issue 4
Open Access

Pharmacological and Biochemical Evaluation of Metformin, Glimepiride, and Voglibose in the Management of Type 2 Diabetes Mellitus.

Dr K Vijay Kumar[1], Dr Brijendre Singh Hindoliya[2], Dr Ashok Kumar Mehra[3] Dr B J Pradeep Kumar[4(Corresponding author)], Dr Mohd Faheem Mubeen[5], Dr S Thamizharasan[6]

1. Associate Professor, Dept. of Pharmacology, Varun Arjun Medical college and Rohilkhand Hospital, Shahjahanpur, Uttar Pradesh.
2. Assistant Professor, Dept. of Biochemistry, Varun Arjun Medical college and Rohilkhand Hospital, Shahjahanpur, Uttar Pradesh.
3. Assistant Professor, Dept. of Biochemistry, RKDF Medical College and Hospital, Bhopal, Madya Pradesh.
4. Professor, Dept. of Biochemistry, Varun Arjun Medical college and Rohilkhand Hospital, Shahjahanpur, Uttar Pradesh.
5. Associate Professor, Department of Pharmacology, Ayaan Institute of Medical Sciences and Teaching Hospital.
6. Professor, Dept. of Pharmacology, Viswabharathi Medical college and Hospital, Kurnool, Andrapradesh.

Corresponding author
Dr B J Pradeep Kumar

Cite this paper as: Dr K Vijay Kumar, Dr Brijendre Singh Hindoliya, Dr Ashok Kumar Mehra, Dr B J Pradeep Kumar, Dr Ashok Kumar Mehra, Dr S Thamizharasan. (2024) Pharmacological and Biochemical Evaluation of Metformin, Glimepiride, and Voglibose in the Management of Type 2 Diabetes Mellitus. *Frontiers in Health Informatics, 13* (4), 428-435

Abstract

Introduction: Poor glycemic control was seen in most of the patients suffering from type 2 diabetes mellitus. Fixed dose combination of Metformin, Glimepiride, and Voglibose prescribed in patients with HbA1c more than 9.0% diabetic patients. The main is to study the effect of triple drug combination therapy in treating type 2 diabetes mellitus patients.

Aim: To study the effect of metformin + glimepiride + voglibose in the treatment of type 2 diabetes mellitus patients.

Material and methods: the present study was carried out on 200 type 2 diabetes mellitus. Patients under inclusion criteria and ready to give informed consent forms were included in the study and treated with the combination of metformin + glimepiride voglibose. All the patients' blood glucose levels and lipid profiles were estimated before taking drugs (baseline) and after 6 months of treatment, all the investigations were done again (after 6 months).

Results: The total number of patients included in the study was 200, among them; the majority was male with the age group of 51 – 60 years. All the patients HbA1c, FBS, PPBS, total cholesterol, triglycerides, HDL, LDL & VLDL. A higher Significant mean reduction was observed in HbA1c, FBS & PPBS ($p<0.005$). on lipid profile significant mean reduction was observed in TC (p 0.042), Triglycerides (p 0.034), LDL (p 0.045) & VLDL (p 0.050) and increased mean was observed in HDL (p0.050) after treatment with a triple-drug combination of metformin, glimepiride, and voglibose respectively.

Conclusion: Triple drug combination of metformin, glimepiride, and voglibose shows significant improvement in blood glucose and lipid levels in type 2 diabetes mellitus patients.

Keywords: Triple Drug Combination Therapy, T2DM

Introduction

Type 2 Diabetes mellitus is a severe metabolic disorder leading to insulin resistance and improper production of insulin from the pancreas, leading to hyperglycemia. Diabetes mellitus is mostly associated with obesity with less physical inactivity, increased blood pressure, and imbalanced blood lipid levels in thrombosis, this causes raised cardiovascular risk. It also causes long-term microvascular and macrovascular complications, which change the quality of human life [1]. Recently in India increase in the diabetic population was observed 2nd to the world diabetic population. As per the report of the International diabetic federation (IDF), In India, almost 72.9 million people were suffering from diabetes in the year 2017 which may increase to 134.3 million by 2045. In India prevalence of diabetes was mostly observed in urban and metropolitan cities [2]. The screening for diabetes should be done in children and adolescents aged 18 years or below and overweight >120 % of IDW. There are also some risk cases where diabetic screening has to be done, patients having a family history of diabetes, prehistory of PCOS, dyslipidemia, hypertension, and a sedentary lifestyle. If a patient having diabetes patients has to take medication lifelong, there are different classes of anti-diabetic drugs used for the treatment of hyperglycemic patients among them the fixed-dose combination of metformin + glimepiride +voglibose.

Voglibose is a class of drugs that belongs to alpha-glucosidase inhibitors used in lowering PPBS. It delays the absorption of glucose. [3]. It reduces the risk of macrovascular complications [4]. Glimepiride, sulfonylurea group of the antidiabetic drug. It is chosen second to metformin as mono-drug therapy [5]. This drug shows its mechanism of action by lowering blood sugar by stimulating the secretion of insulin by pancreatic beta cells and increasing intracellular insulin receptors. [6]. Metformin is a first-line drug in the treatment of T2DM [7]. It can be prescribed in patients with overweight and is also used in the treatment of polycystic ovary syndrome [8]. Metformin shows its action by decreasing glucose production in the liver, increasing insulin sensitivity, and reducing appetite and caloric intake. The drug taken in this study belongs to three different classes of antidiabetic drugs. The main aim is whether a triple-drug combination of antidiabetic drugs shows significant improvement in blood glucose levels and lipid profile in diabetic patients whose HbA1c ranges more than 9.0%.

Material & Methods:

Study place: This study was carried out in the Department of Pharmacology in association with the Department of General Medicine Rama Medical College, Hospital & Research Centre, Kanpur, U.P. The study was approved after obtaining permission from the Institute Ethics Committee.

Study population: The total number of patients included in the study was 200 type 2 diabetes mellitus patients.

Inclusion criteria:

1. Age between 30 – 80 years.
2. Patients with type 2 diabetes mellitus
3. Patient ready to give informed consent form.

Exclusion criteria:

1. Patient already taking antidiabetic drugs
2. Age less than 30 years
3. Patient not ready to give informed consent form
4. Patient with diabetes with other complications.
5. Patient with surgery leading to diabetes

Study design: A total of 200 patients have been prescribed a combination of metformin + glimepiride +voglibose. for type 2 diabetes mellitus patients.

Methodology: the present study was carried out on 200 type 2 diabetes mellitus. Patients under inclusion criteria and ready to give informed consent forms were included in the study and treated

with the combination of metformin + glimepiride + voglibose for 6 months. All the patients' blood glucose levels and lipid profiles were estimated before taking drugs (baseline) and after 6 months of treatment, all the investigations were done again (after 6 months). All the patients were informed about adverse drug effects like hypoglycemia and relevant treatment to them.

Statistical analysis: Statistical analysis was done by using SPSS software. For comparing the group (before and after treatment) paired t-test was conducted. On comparing different groups unpaired t-test was done. Significance levels for tests were determined as 95% ($P< 0.005$) highly significant and $p <0.05$ significant.

Results

Table No 01: Tabular column represents the gender of patients with type 2 diabetes mellitus.

Genders	No of patients	% number of patients
Male	119	59.5 %
Female	81	40.50%
Total no of patients	200	100.00%

Figure No 01: Graphical representation of number of patients with T2DM.

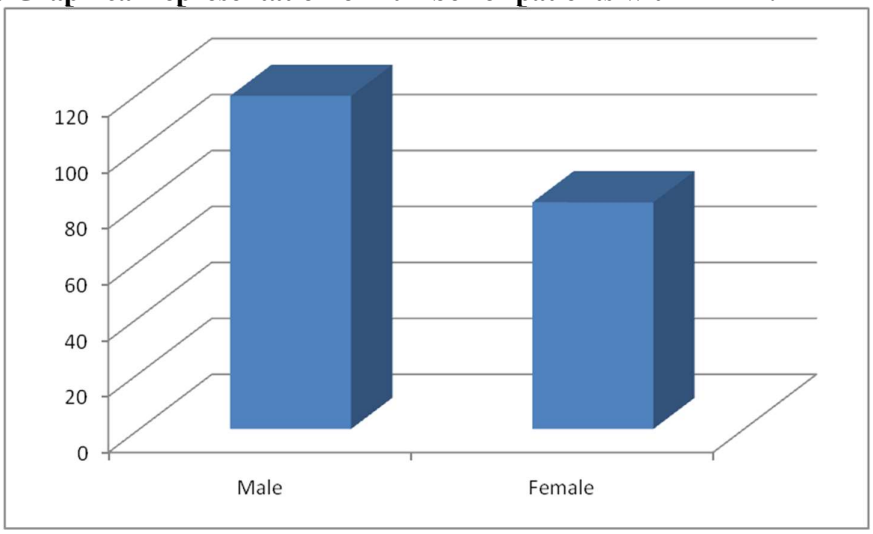


Table No 02: Tabular column represents the age group in patients with type 2 diabetes mellitus

Age group of the patients	No of patients with T2DM	% No of patients with T2DM
30 – 40 years	18	9.00%
41 – 50 years	34	17.00%
51 – 60 years	65	32.50%
61 – 70 years	45	22.50%
71 – 80 years	38	19.00%
Total no of patients	200	100.00%

Figure No 02: Graphical representation of number of patients with different age groups.

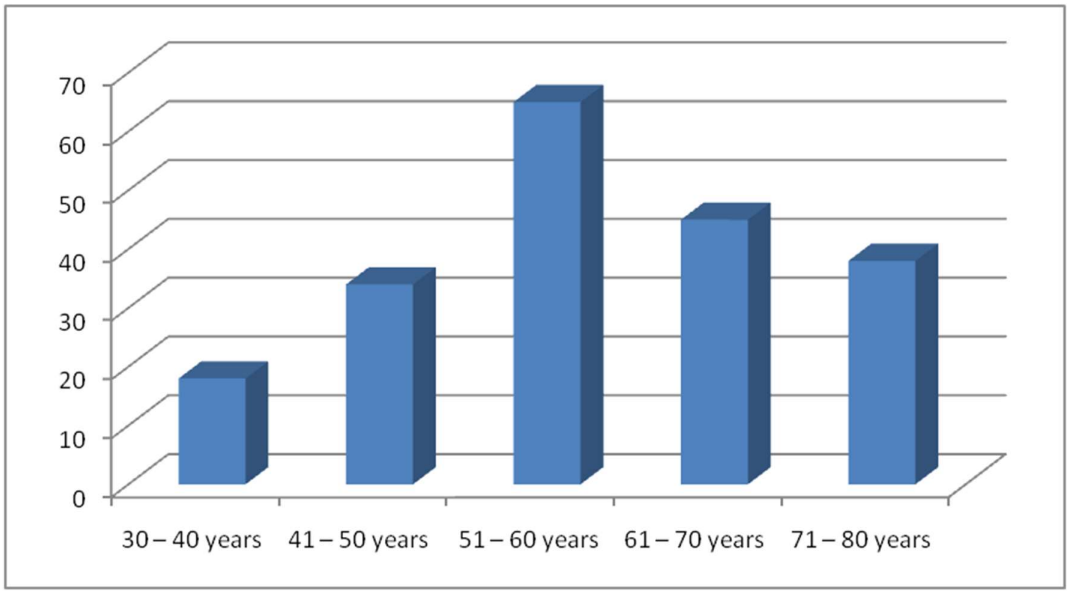


Table No 03: Tabular column represents the symptoms in type 2 diabetes mellitus

Symptoms	No of patients having symptoms	% No of patients having symptoms
Polyurea	48	29.81%
Polydipsia	32	19.87%
Polyplegia	28	17.39%
Weight loss	22	13.66%
Vomiting	8	4.96%
Blurring of vision	14	8.69%
Tingling hands	21	13.04%
Vaginal infection	8	4.96%
Total no of symptoms observed in 161 patients	181	88.95%
Total number of symptoms	161	80.50%
No of patients not having symptoms	39	19.50%
Total no of patients	200	100%

Figure No 03: Graphical representation of symptoms observed in T2DM patients

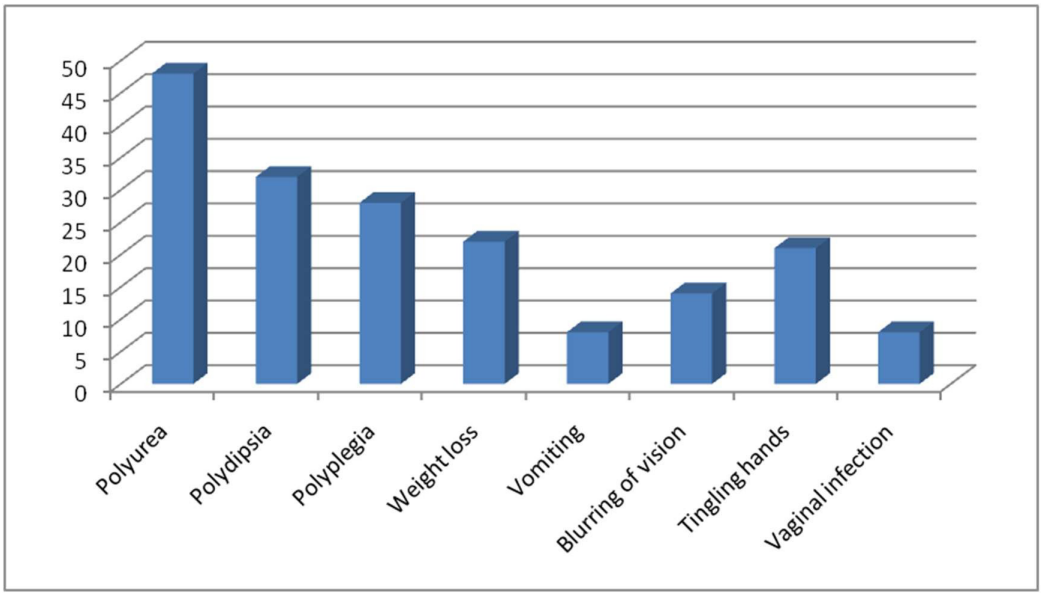


Table No 04: Tabular column represents the blood glucose levels after 6 months of treatment.

Blood glucose levels	Baseline	6 Months	MD±SD	p-value
HbA1C (%)	9.00±0.393	6.12±0.781	2.88±0.39	< 0.005
FBS (mg/dl)	158.23±11.27	128.52±12.48	29.71±1.21	
PPBS (mg/dl)	238.82±13.40	193.47 ± 15.48	45.35±2.08	

Figure No 04: Graphical representation of baseline and 6 months values after treatment with metformin + glimepiride +voglibose.

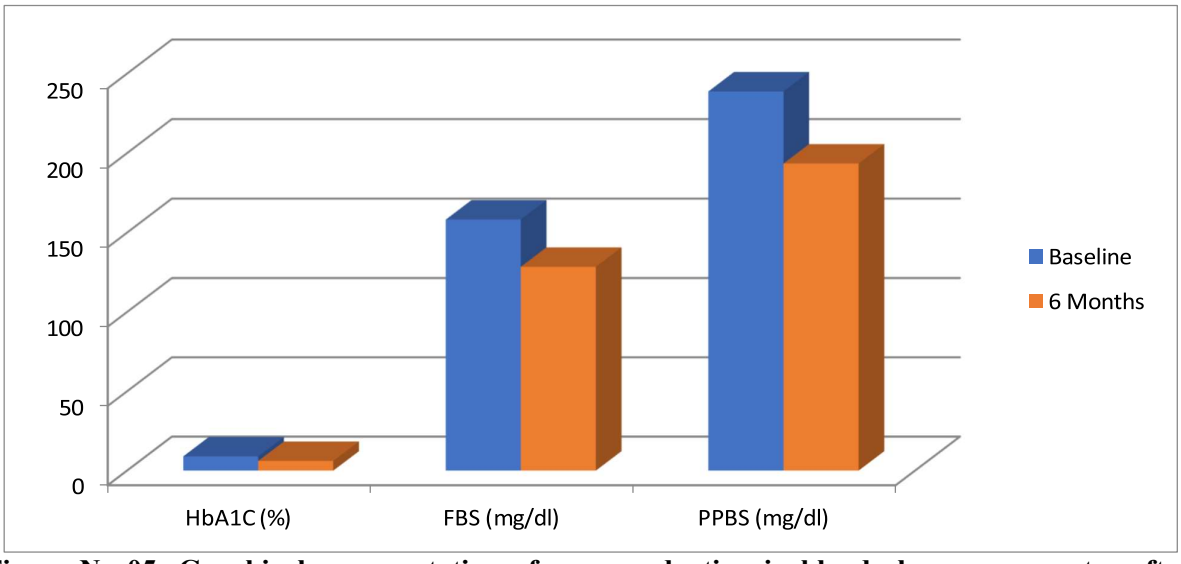


Figure No 05: Graphical representation of mean reduction in blood glucose parameter after treatment with metformin + glimepiride +voglibose.

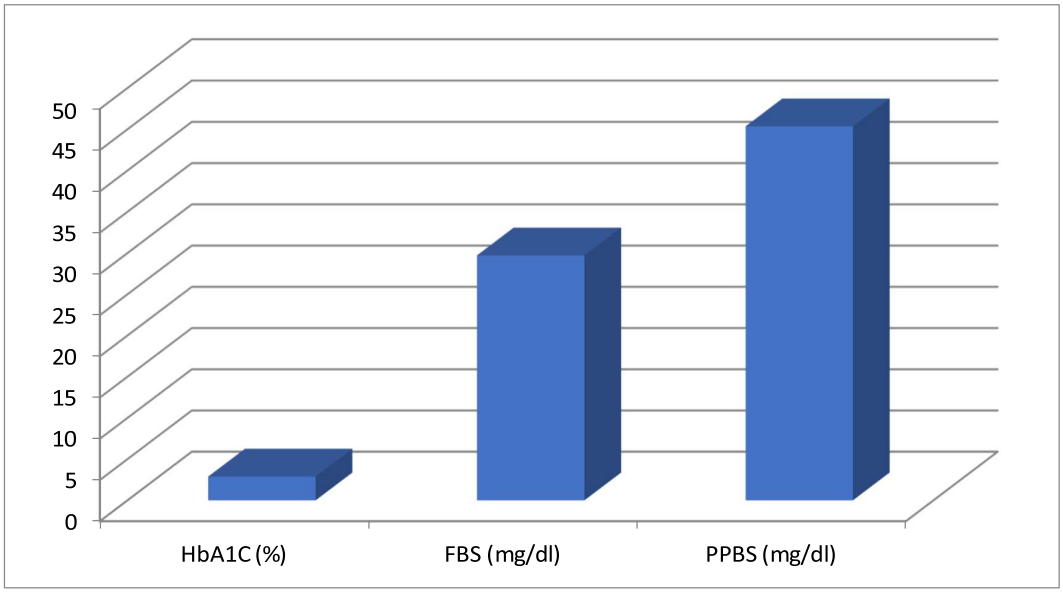


Table No 05: Tabular column represents the baseline and 6 months after treatment in lipid profile

Lipid profile	Baseline	6 Months	MD±SD	p-value
TC (mg/dl)	189.17 ± 10.67	164.47 ± 8.50	24.70±2.17	0.042
TG (mg/dl)	149.17 ± 12.28	129.76 ± 15.47	19.41±3.19	0.034
HDL (mg/dl)	42.82 ± 9.74	52.88 ± 9.41	-10.06±0.33	0.050
LDL (mg/dl)	157.17 ± 17.06	138.88 ± 9.87	18.29±7.19	0.045
VLDL (mg/dl)	42.94 ±2.43	32.76 ± 3.63	10.18±1.20	0.050

Figure No 06: Graphical representation of baseline and 6 months ranges at baseline and 6 months after treatment with metformin + glimepiride +voglibose.

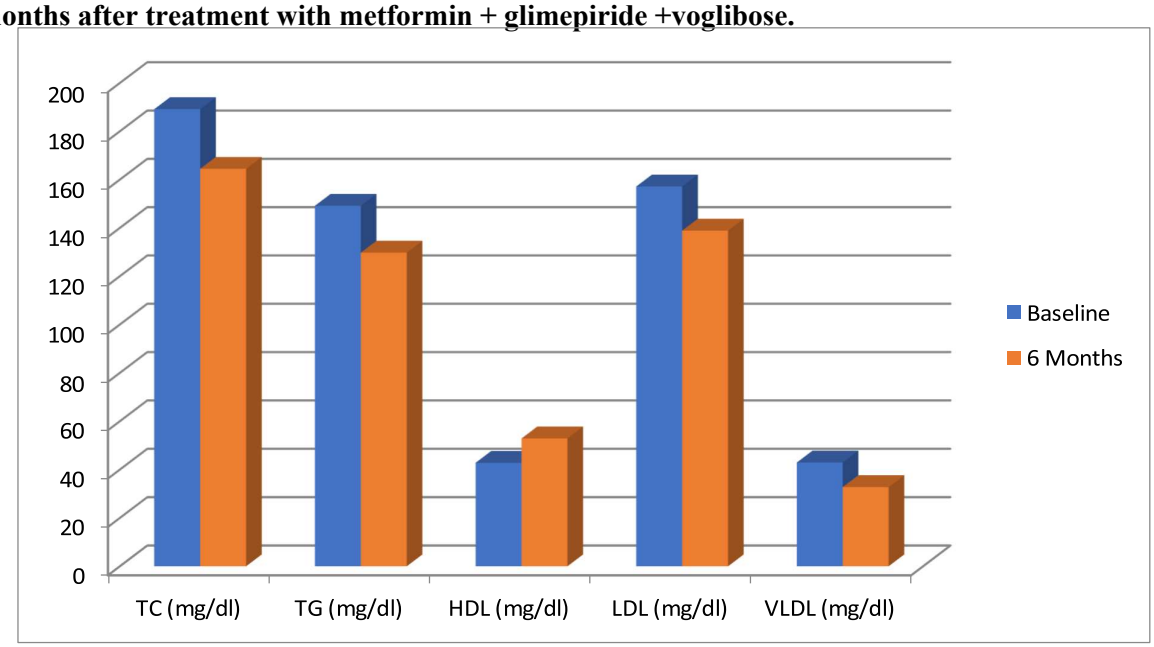
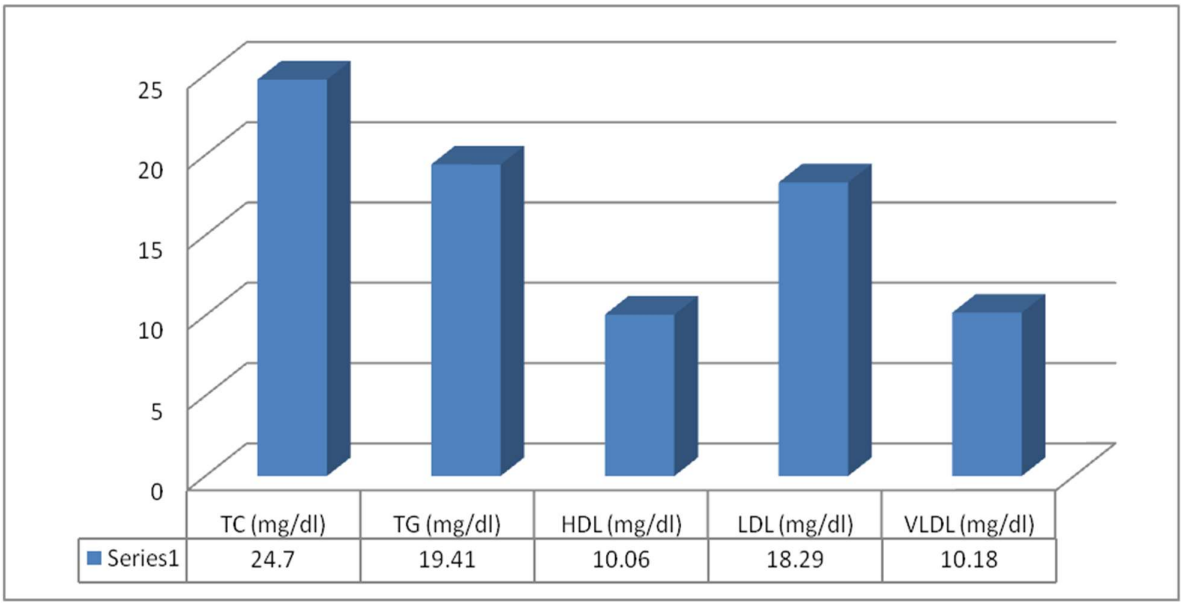


Figure No 07: Graphical representation of mean reduction in lipid profile after 6 months of treatment with metformin , glimepiride & voligbose



Discussion: The study was carried out on 200 type 2 diabetes mellitus patients. The majority of the patients were male 59.5% followed by females 40.50% respectively. As per the age group of the patients, the majority of the patients were 51 – 60 years 32.50%, followed by 61 – 70 years 22.50%. A total of 161 patients have diabetic symptoms such as Polyurea 29.81%, Polydipsia 19.87%, polydipsia 17.39%, and weight loss 13.66 %. Vomiting 4.96%, blurring of vision 8.69%, tingling hands 13.04%, and vaginal infections 4.96%. We have 39(19.50%) patients having no symptoms respectively. On monitoring the blood glucose levels, HbA1c at baseline was 9.00 ± 0.393 after 6 months 6.12 ± 0.71 with a mean reduction was 2.88 ± 0.39, fasting blood glucose levels at baseline were 158.23 ± 11.27 after 6 months 128.52 ± 12.48 with a mean reduction of 29.71 ± 1.21 and on postprandial blood glucose levels at baseline 238.82 ± 13.40 after 6 months 193.47 ± 15.48 with a mean reduction of 45.35 ±2.08. After 6 months of treatment blood glucose levels showed a high statically significant mean reduction in HbA1c, FBS & PPBS ($p<0.00$ 5). On the estimation of the lipid profile of total cholesterol at baseline 189.17 ± 10.67after 6months 164.47 ± 8.50 with a mean reduction of 24.70 ± 2.17 showing statically significant (p 0.042), triglycerides at baseline 149.17± 12.28 after 6 months 129.76 ± 15.47 with a mean reduction of 19.41 ±3.19 showing statically significant (p 0.034), HDL at baseline 42.82 ± 9.74 after 6 months of treatment 52.88 ± 9.41, a significant increase in mean levels -10.06 ± 0.33 showing statically significant (p 0.050), LDL at baseline 157.17 ± 17.06 after 6 months 138.88 ± 9.87 with a mean reduction of 18.29 ± 7.19 showing statically significant (p 0.045) and VLDL at baseline 42.94 ± 2.43 after 6 months after treatment 32.76 ± 3.63, the significant mean reduction in 10.18 ± 1.20 showing statically significant (p 0.050) respectively. Our study coincides with the study of Krishna Murti et al (2016) in his study he concluded that on therapy of voglibose with a dual drug combination of metformin and glimepiride showed significant improvement in HbA1c, FBS, and PPBS when compared with a dual drug combination of metformin and glimepiride. Voglibose decreases total cholesterol, triglycerides, and LDL, and increases HDL significantly where no effect was observed on blood urea level. Arif A. Faruqui (2016) mentioned that a combination of metformin with voglibose significantly improves blood glucose levels in patients suffering from type 2 diabetes mellitus

Conclusion In the present study the mean average HbA1c was 9.0%, and the combination of metformin, glimepiride, and voglibose was prescribed showing significant improvement in blood sugar and lipid levels in type 2 diabetes mellitus patients.

References

1. NICE (2015) Type 2 diabetes in adults: management (NG28). NICE, London.
2. MasharaniUmesh, Diabetes Mellitus & Hypoglycemia Current Medical Diagnosis Treatment 2021: McGraw-Hill – 3107-08,3089-3099.
3. Chen X, Zheng Y, Shen Y. "Voglibose (Basen, AO-128), one of the most important alpha-glucosidase inhibitors". Current Medicinal Chemistry. 2006; 13 (1): 109–16.
4. Dabhi AS, Bhatt NR, Shah MJ "Voglibose: an alpha glucosidase inhibitor". Journal of Clinical and Diagnostic Research. 2013;7 (12): 3023–7
5. Nissen SE, Nicholls SJ, Wolski K, et al. "Comparison of pioglitazone vs glimepiride on progression of coronary atherosclerosis in patients with type 2 diabetes: the PERISCOPE randomized controlled trial". JAMA. 2008;299 (13): 1561–73
6. Davis, Stephen N. (2005). "60. Insulin, oral hypoglycemic agents, and the pharmacology of the endocrine pancreas". In Brunton, Laurence L.; Lazo, John S.; Parker, Keith L. (eds.). Goodman & Gilman's The Pharmacological Basis of Therapeutics. New York: McGraw-Hill. p. 1636.
7. Draznin B, Aroda VR, Bakris G, Benson G, Brown FM, Freeman R, et al."9. Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes-2022". Diabetes Care. 2022;45 (1): S125–S143.
8. Cosentino F, Grant PJ, Aboyans V, Bailey CJ, Ceriello A, Delgado V, et al. “2019 ESC Guidelines on diabetes, pre-diabetes, and cardiovascular diseases developed in collaboration with the EASD". European Heart Journal. 2020;41 (2): 255–323.
9. Coll AP, Chen M, Taskar P, Rimmington D, Patel S, Tadross JA, et al.. "GDF15 mediates the effects of metformin on body weight and energy balance". Nature. 2020;578 (7795): 444–448.
10. Day EA, Ford RJ, Smith BK, Mohammadi-Shemirani P, Morrow MR, Gutgesell RM, et al.. "Metformin-induced increases in GDF15 are important for suppressing appetite and promoting weight loss". Nature Metabolism. 2019;1 (12): 1202–1208.
11. Krishna Murti, Manoj Kumar Sethi, Akalanka Dey, Chandra Sekhar Lal, Krishna Pandey and Pradeep Das, Addition of Voglibose to Glimepiride and Metformin have Better Glucose Control in Diabetics: A Prospective, Parallel-group and Open-label Comparative Study. International Journal of Pharmacology, 2016;12: 422-428.