Original Research Article

Comparative study of voglibose 3mg vs repiglinide 1mg in postprandial hyperglycemia in newly diagnosed type II diabetes mellitus patients in Telangana

R Sreedhar[1*], R Aruna[2]

[1]Associate Professor, Department of Pharmacology, Kamineni institute of Medical sciences. Narketpally, Nalgonda(dist) – Telangana, Andhra Pradesh, INDIA.

[2]Associate professor, Department of Pathology chalmeda Ananda Rao institute of Medical Sciences. Karimnagr Telangana, Andhra Pradesh, INDIA.

Email: drsreedharkrnr@gmail.com

Abstract

Background: Two groups patients of TYPE 2 DM were treated with Repaglinide and voglibose in postprandial hyperglycemia in newly diagnosed patients of different age groups and in both sexes. **Methods:** 250 patients were taken in to study, and they are divided in to 2 groups, group A and B. A group was treated with Repaglinide 1mg and B group was treated with voglibose .3mg. Blood sugar was analyzed, both fasting and postprandial by auto- analyzer by oxidase methods and hbA1c was analyzed by capillary electrophoresis method. **Results:** hbA1c analyzed in both A and B groups before treatment, and after 3 month of the treatment. And mean values of both groups treated with different drugs (Repaglinide and voglibose) had significant p value ($P<0.01$). In FBS before treatment and after 3 month of the treatment in both groups were highly significant mean value ($P<0.01$).In comparative Study of PPBS before treatment and after 3 months in both groups were highly significant statistically ($P<0.01$). BMI was raised in group A (Repaglinde) as compared to group B (voglibose) and least adverse reactions were observed in patients of group A (Repaglinide) **Conclusion:** Although both drugs were equally effective in controlling post prandial hyperglycemia but Repaglinide proved to be better because of its least adverse reactions.

Key Word: FBS, PPBS, HbA1C, Type-II DM, Telangana.

[*]**Address for Correspondence:**
Dr. R Sreedhar, H No- 10-3/14/2. Ratna Residency, Sripuram colony- Karimnagar -505001, Telangana, Andhra Pradesh, INDIA.
Email: drsreedharkrnr@gmail.com

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INTRODUCTION

Type-2diabetes is a common metabolic disorder and chronic progressive disease, in which hyperglycemia occurs due to imbalance between the body's need of insulin and its ability to produce it by beta cells of pancreas. The progressive nature of the disease results from a continuing deterioration in pancreatic beta cells function. and development of hyperglycemia[1]. The first step in the deterioration of glucose homeostasis is the loss of postprandial glycemic control, which is followed by a progression to morning hyperglycemia and eventually to sustained nocturnal hyperglycemia. Impaired glucose tolerance test is considered as pre-diabetic stage and it may occur years before elevated fasting plasma glucose (FPG) level are observed[3]. It is defined as 2 hours postprandial plasma glucose (PPG) levels between 140 and 199mg/dl following a 75gm oral glucose tolerance test.[4] Postprandial hyperglycemia can be the rate-limiting factor for achieving control. There is also evidence suggesting that, postprandial hyperglycemia may be an independent risk factor for cardio vascular disease, cerebral stroke,diabetic retinopathy, diabetic nephropathy, renal failure and neurological complications[5]. Hence a novel drug Repaglinde is non-sulfonylurea, insulin secretogens are given in such patients. hypoglycemia does not cause progressive falls in glomerular Filtration Rate (GFR)[6]. Drug Voglibose is an alpha-glucosidase

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inhibitor (AGI) provides another therapeutic option for patients with type-2 diabetes mellitus in which glucose control is inadequate, despite of diet control alone or with pharmacological therapy with sulfonylureas and biguanide. Hence these both drugs were given in different groups of type-II DM and their efficacy and advantages disadvantage adverse effects were also studied.

MATERIAL AND METHODS

It is comparative, prospective randomized study done at kamineni institute of medical sciences Narketpally Nalgonda –Telangana state

Inclusive criteria: The patients with newly diagnosed as type 11 DM. Patients with postprandial blood sugar levels ranges from 180mg/dl to 250mg/dl Patients age ranges from 35 yrs to 65 yrs.

METHODS

About 250 patients were taken in to study they were divided in to 2 groups by lottery system. group A, 125 patients were treated with Repaglinide 1mg tds and, group B 125 patients were treated with voglibose 0.3 mg tds. Blood sugar was analyzed fasting and postprandial on semi auto analyzer by glucose oxidase method. HbA_1C analysis is done by capillary electrophoresis or chromatography method. The patients having adverse effects to drugs, the dosage was reduced or divided. In severe adverse effects the drugs was discontinued. The duration of study was about 2 years This research paper was approved by ethical committee of Kamineni Medical college Narketpally. Nalgonda- Telangana

Exclusion criteria: Chronic DM- II patients, pregnant women and lactating mothers, patients having history of MI, Ulcer of GIT, patients with history of allergy to anti diabetic drugs. patients taking the antidepressant drugs were excluded from the study.

Statistical analysis: various parameters of two groups, group A (treated with Repaglinide 1mg) and group B (treated with voglibose .3 mg) were compared after three months viz, FBS, PPBS, HbA_1C with SPSS software 2007. The ratio of male and female was 2:1.

OBSERVATION AND RESULTS

Table 1: Study of Body mass Index (BMI) in group A- mean value before treatment was 27.6 ± 2.32 and 29.8 ±1.30 after treatment t test value was 9.24 and P value was highly significant. In group B- mean value before treatment was 22.8 ±2.30 and 26.9±1.18 after the treatment t test value was 8.21 and P value was highly significant (P<0.01)

Table 1: Comparative study of BMI in both groups before after treatment

Group A RPG(125)	**Before treatment After treatment**	**Mean value 27.6(SD ± 2.32) 29.8 (SD ±1.30) t=9.24**	**P<0.01**
Group B VGB(125)	Before treatment After treatment of 3 months	28.8(SD ± 2.30) 26.9 (SD± 1.18) t=8.21	P<0.01

Total No of Patients -250

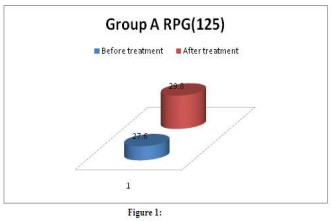

Figure 1:

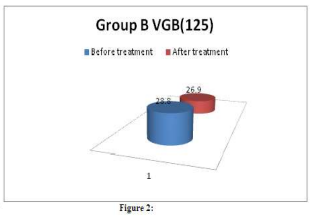

Figure 2:

Table 2: Comparative study HbA1c in both A and B groups- In group mean value before treatment 8.02 ±0.420 and after three months of the treatment it was 7.03±0.510 t test value was 16.7 and P value was highly significant (P<0.01) In group B-mean value before treatment was 8.01± 0.42 and after three months of treatment was 7.12 ± 0.462 t test value was 16.2 and P value was highly significant (P<0.01)

Table 2: Comparative study of HbA_1C patients

Group A RPG(125)	**Before treatment After 3 months treatment**	**Mean value 8.02(SD±0.420) 7.03(SD±0.510) t=1.67**	**P<0.01 P<0.01**
Group B VGB (125)	Before treatment After 3 months treatment	8.01(SD±0.402) 7.12(SD±0.462) t=1.62	P<0.01 P<0.01

Total No of Patients -250

Mean value of before treatment were higher than treatment for 3 months hence both values were statistical highly significant (P<0.01)

Table 3: Comparative study of FBS(Fasting Blood sugar) Group A-mean value before treatment was 139±4.1 and after three months of the treatment 123.9±5.08 t test value was 27.76and P value was highly significant (P<0.01) In group B- mean value before treatment was 141.82±5.08 and after three monthly of treatment was 126.1± 4.02 t test value was24.2 and P value was highly significant (P<0.01)

Table 3: Comparative study of FBS in groups A and group B patients

Group A RPG (125)	Before treatment After3 months treatment	Mean value 139.5(SD±4.10) 123.9(SD±5.08) t=27.6	P value P<0.01
Group B VGB (125)	Before treatment After 3 months treatment	141.8(SD±5.08) 126.12(SD±4.02) t=24.2	P<0.01

Total No of Patients -250

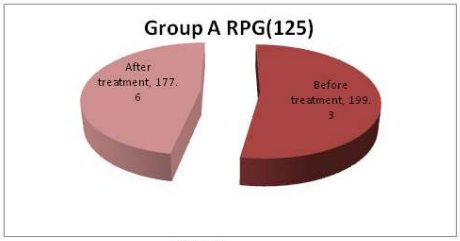

Figure 3:

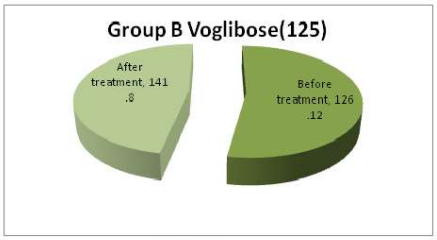

Figure 4:

Mean values of both groups were higher before treatment than after treatment hence both value were highly significant statistically (P<0.01)

Table 4: Comparative study of PPBS (postprandial Blood sugar) Group A-mean value before treatment was 199.3±10.2 and mean value after three months of the treatment was 177.6 to 7.8 t test value was16.8 and P value was highly significant (P<0.01) In group B- mean value before treatment was 207.3 ± 9.5 and after three months of treatment was 186.7±10.03 t test value was16.6 and P value was highly significant (P<0.01)

Table 4: Comparative study of PPBS (Postprandial blood sugar)

Group A RPG(125)	Before treatment After3 months of treatment	Mean value 199.3(SD±10.26) 177.6 (SD± 7.82) t=16.8	P value P<0.01
Group B VGB (125)	Before treatment After 3 months treatment	207.3(SD ± 9.56) 186.7(SD±10.03) t=16.6	P<0.01

Total No of Patients -250

Postprandial blood sugar value before treatment were higher in both groups hence both values are statistically highly significant (P<0.01)

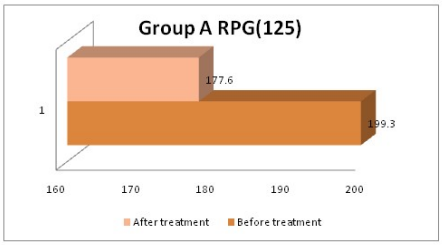

Figure 5:

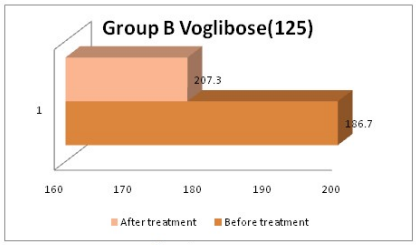

Figure 6:

Table-5- Study of adverse drug reactions in both groups are Diarrhea in group A- 4(3.2%). In group B- hypoglycemia 3 (2.4%) Nausea, vomiting 2(1.6%) Abdominal distention/flatuance-2(1.6%) were reported

DISCUSSION

In the present study of comparison of Repaglinide and voglibose in postprandial hyperglycemia in newly diagnosed type-II DM patients of Telangana. In groups mean value 27.6±2.32 before treatment 29.8±1.30 after treatment t test value was 9.24 and P value was highly significant. In group B-mean value before treatment was 28.8±2.30, 26.9±1.18 after treatment the t test value was8.21 and P value was highly significant (P<0.01) (Table-1) In the comparative study of HbA1c in group A- mean value before treatment was 8.02±0.420, 7.03±0.510 t test value was16.7 and (P<0.01), after 3 months of the treatment. In group B, mean value before treatment was 8.01±0.402 and 7.12±0.462 after 3 months of the

treatment t test value was 16.2 and P value was highly significant (P<0.01).(Table-2).In the comparative study of FBS in both A and B group B mean value before treatment was 141.8±5.08 and after 3 months of the treatment was 126.12±4.02 t test value was 24.2 and P value was highly significant (P<0.01) In group mean value was before treatment 139.5±4.10 and 123.9±5.08 after treatment t test value was24.2 and P value was highly significant (P<0.01) (Table-3) In the comparison of PBS both A and B groups- In groups A- mean value before treatment was 199.3±10.2 after 3 months 177.6 ± 7.82 t test value was16.8 and P value was highly significant (P<0.01)In group B- mean value before treatment was 207.3± 9.56 and after 3 months was 186.7 ± 10.3 t test value was 16.6 and P value was highly significant (P<0.01)(Table-4) these findings were more or less in agreement with previous studie[7,8,9]. As postprandial hyperglycemia develops early in the course of Type-2 DM and is often evident even before fasting plasma glucose (FPG) elevation was reported[10]. One of the proposed mechanisms of diabetic vascular disease is the observed is, increase in oxidative stress that occurs following consumption of meals that produce a high level of glycemia[11]. This oxidative stress has been shown to induce endothelial dysfunction and increase inflammation, vasoconstriction and carotid tunica intima-media thickness.[12] PPBG control is important not only for regulating the hyperglycemia but also to decrease cardio –vascular risk. Currently five groups of drugs are used n the treatment of Type-2 D.M, that primary target postprandiall hyperglycemia which are short acting insulins, Meglitinides, DPP4 inhibitors, alpha glucosidase inhibitors and GLP-1 analogous[13]. The loss of first phase of insulin Secretion response, along with insulin resistance results in development of PPHG. Voglibose is more potent and tolerant alpha-glycosidase inhibitor (AGI) as compared to acarbose and miglitol but increases starch amounts in small intestine. This undigested and un-absorbed starch in faces leads to gastro-intestinal side effects like flatuance abdominal dissension, gases etc[14] Hence the fixed dosage combination of repaglinide and voglibose could be a better option in order to improve and prevent future micro and macro vascular diabetic complications in patients with postprandial hyperglycemia.

SUMMARY AND CONCLUSION

The present study of comparison of Repaglinide 1mg and voglibose. 3mg in postprandial hyperglycemia in newly diagnosed type-II diabetes patients of Telangana, has proved that both drugs are equally effective to treat and both drugs can be used with fixed dose combination. because in type-II-D.M viscosity of blood is raised and there will be impairment of blood in the micro and macro vascular circulation which causes multiple cardio-vascular complications which prove to be fatal. But this study demands further genetic, nutritional, patho-physiological, pharmacological study because the factors which elevates the hyperglycemia is still un-clear

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