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Comparative Study of Change Of PPBS With Voglibose and Teneligliptin On Ongoing Metformin Monotherapy

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ABSTRACT

Metformin is a biguanide used as first line treatment of type 2 diabetes mellitus. When metformin alone is unable to control glycaemic status properly then additional drug needs to be added. Some of the additional drugs reduce primarily fasting blood sugar (FBS) and some reduce post prandial blood sugar (PPBS). Voglibose and Teneligliptin are primarily capable of reducing PPBS. In this background the present study was planned for comparative study of voglibose and Teneligliptin to reduce PPBS ongoing metformin monotherapy. It was a hospital based longitudinal interventional study among patients attending General Medicine OPD of ICARE medical college with uncontrolled hyperglycemia and whose HbA1c was above 7 but upto 10% and PPBS above 200mg/dl. One group of patients were given Voglibose 0.3mg TDS and another group of patients were given Teneligliptin 20mg BD in addition to previous dose of metformin. After 8 weeks of starting additional drug again PPBS level was assessed for each patient. It was found that mean PPBS level at the beginning was 296 mg/dl for voglibose group and 288mg/dl for Teneligliptin group. There was no significant difference between these two. After 8 weeks of therapy the mean PPBS level of voglibose group was significantly higher than Teneligliptin group. However both groups showed significant reduction of PPBS as compared to starting. The study highlights the ability to reduce PPBS is more with Teneligliptin 20mg BD than Voglibose 0.3mg TDS.

Keywords: PPBS, Voglibose, Teneligliptin

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INTRODUCTION

Metformin is a Biguanide which is used as first line therapy of type 2 diabetes mellitus patients.When diabetes is not controlled by physical exercise and dietary restriction only then first drug to be used is Metformin. Metformin is the drug for treatment of diabetes mellitus till glycaemic level is within normal limit. When Metformin alone is not able to control blood glucose level properly then additional drug is to be added. The judicial use of additional drug is dependent on type of hyperglycaemia. Hyperglycaemia may be baseline (fasting) or after taking food (post prandial). Different drugs are used for treatment of fasting and post prandial hyperglycaemia control. Alpha glucosidase inhibitor, dipeptidyl peptidase 4 (DPP 4 inhibitor) are some of the drugs which are mainly capable of reducing postprandial blood glucose. The present study was aimed to find out the comparative ability to reduce post prandial blood glucose with voglibose (one alpha glucosidase inhibitors) and teneligliptin (DPP 4 inhibitor).

MATERIALS AND METHOD

Type of study:

It was a hospital based interventional longitudinal study.

Study area:

All patients giving informed consent attending General Medicine OPD of ICARE Institute of Medical Sciences and Research with diabetes and on Metformin monotherapy with uncontrolled hyperglycaemia were included in the study till the required sample size is achieved.

Sample size:

Percentage of patients requiring additional antidiabetic medication over Metformin monotherapy is 38%[1]. So prevalence of use of additional drug in treating Type 2 DM (p) is 38%=0.38

So, (1-0.38)=0.62 is the number of patients not requiring additional drug over Metformin (q).

If we allow error of 10% (L)

So, using the formula $4pq/L^2$= (4*0.38*0.62)/(0.1*0.1)=94

So, required sample size is 94.

Considering 10% patients would be lost to follow up or discontinue the drug due to different reason, total required sample is 94*1.1=103.4.

So 104 patients were included in the study.

Sample design:

52 patients were included in each arm: Voglibose-Metformin combination therapy and Teneligliptin-Metformin combination therapy. The selection of patients in each arm was done by randomization using lottery method.

Study technique:

Patients were randomized in two groups. One group received Teneligliptin 20mg twice daily in addition to metformin and the other group received voglibose 0.3mg thrice daily in addition to metformin. PPBS assessed before introduction of additional drug and 8 weeks after starting additional drug.

Inclusion criteria:

I. Persons having inadequate glycaemic control with HbA1c above 7% but below 10%

ii. Persons on metformin monotherapy

iii. Type 2 Diabetes mellitus

iv. Ambulatory patients

v. Patients having PPBS above 200mg/dl

vi. Patients who can be followed up

Exclusion criteria:

I. Type 1 Diabetes mellitus

II. Isolated rise of fasting blood sugar (FBS)

III. Non ambulatory patients

IV. HbA1c above 10%

RESULTS AND DISCUSSION

Figure1 shows the mean level of post prandial blood sugar (PPBS) before starting additional drug. There were two study groups. Group 1 received Voglibose and group 2 received Teneligliptin. Mean PPBS level of Group 1 was 296mg/dl and of Group 2 was 288mg/dl. There was no significant difference between mean PPBS level between these two groups.

Figure 2 shows mean level of PPBS 8 weeks after starting additional drug. For Group 1 it was 218 mg/dl and for Group 2 it was 166 mg/dl. Now the difference between these two is statistically significant ($p<0.05$) which indicates that people belonging to Group 1 were having significantly higher level of PPBS than people belonging to Group 2. So after completion of 8 weeks therapy with additional drug, people receiving Teneligliptin had significant lower level of PPBS than people receiving Voglibose.

Figure 3 shows the change of level of PPBS with these two additional drugs by a line diagram. The starting point is before adding additional drug and end point is after 8 weeks of continuing additional drug. It was seen that with both drugs the level of PPBS have decreased. It was further noticed that the change of PPBS with Voglibose was less than change of PPBS with Teneligliptin. This difference was also found to be statistically significant with $p<0.05$.Statistical test done was unpaired t test.

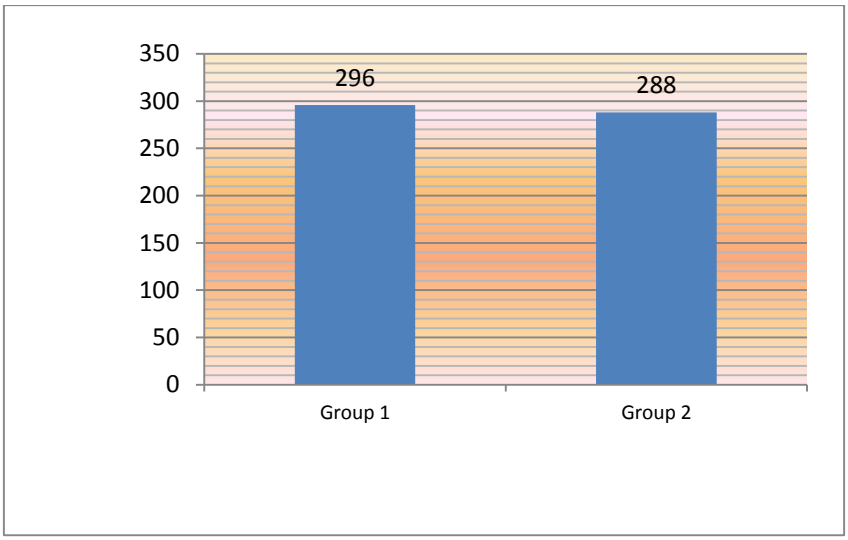

Figure 1: Mean level of PPBS before starting additional drug

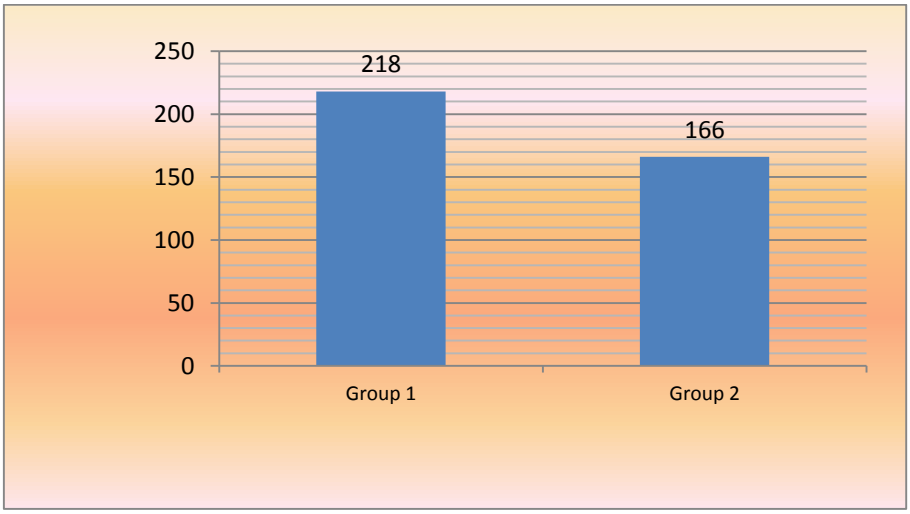

Figure 2: Mean level of PPBS 8 weeks after starting additional drug

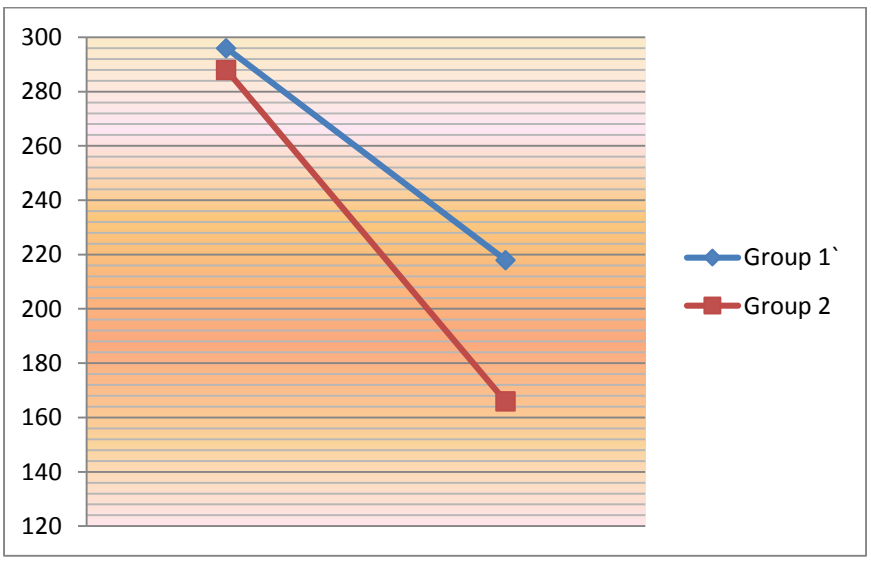

Figure 3: Change of mean PPBS level with additional drug

DISCUSSION:

Among all DPP4 inhibitors Sitagliptin was first approved in 2006. Gradually more and more DPP4 inhibitors were developed[2]. But one of the major restricting factors of their use is their

cost. Due to high cost of DPP4 inhibitors poor patients often are unable to continue these for long time. Unlike other DPP4 inhibitors Teneligliptin has much lower cost. So in rural India it's use is popular considering it's compliance among poor patients. Teneligliptin which is classified as peptidomimetic has a unique structure having five consecutive rings[3]. So it acts on S2 extensive subsiteof DPP4 and this interaction increases its potency and selectivity[4].

Voglibose belongs to class of comparative alpha glucosidase inhibitors which was discovered in 1981[5]. Voglibose causes reversible inhibition of membrane bound intestines alpha glucosidase which hydrolyze oligosaccharides and disaccharides to glucose and other monosaccharides in the brush border of small intestine. So voglibose delays the absorption and digestion of dietary polysaccharides by reversibly inhibiting carbohydrate digestive enzymes like sucrose, maltose, zomaltose etc ultimately resulting in reduction of PPBS.

Teneligliptin is able to lower the PPBS significantly in 4 weeks compares to placebo. Teneligliptin 20mg OD is found to be more potent than Voglibose 0.2mg TDS[6]. The present study highlights the overall PPBS lowering effect of Teneligliptin 20mg BD is more than Voglibose 0.3 mg TDS. But both drugs lower PPBS level significantly over metformin monotherapy.

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