Voglibose and its significance in prediabetes: An observational study

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Abstract
Aim: to achieve glycemic control in prediabetic patient with Alpha glucosidase inhibitors who are risk of developing frank diabetes mellitus.

Material and Methods: In the present study a total of 150 prediabetic patients were selected out of which only 100 participants were eligible for study. Inclusion Criteria: 1) Age: 20-60yrs, 2) FBS: 101-125mg/dl, PPBS: 141 -199mg/dl, 3) BMI: 24-29 4) HbA1c: 5.7-6.4%. Exclusion Criteria: 1) Known Diabetic 2) Any h/o of intake of oral Hypoglycemic Agents 3) Preexisting CAD, Renal Dysfunction, Hepatic Dysfunction, Gastro-intestinal Disorders.

Results: 100 eligible patients were enrolled as per Inclusion criteria, they were divided into two groups, Group 1 (n=53) was placed on Diet, lifestyle modification and Voglibose 0.3mg twice a day, whereas the Group B (n=47) was placebo group. The mean duration of treatment was 24·6 weeks (SD 18.4)—i.e.23.6 weeks (17·5) for voglibose and 25·4 weeks (18.9) for placebo. In group A (n=53), there were 23 males (43.39%), and 30 female subjects (56.60%), whereas in the placebo arm (n=47), there were 20 males (42.55%), 27 Female (57.44%). In the analysis, we found that patients on voglibose was better and the glycemic control was within the standard recommended lines than placebo in individuals

Conclusion: A systematic approach and close monitoring that increased the adherence to medication, diet, and counselling would help in better glycemic control and prevent long term complication. In patient with prediabetes, early intervention with medication can prevent long term complication and also prevents or delays the onset of frank diabetes mellitus.

Keywords: diabetes mellitus, impaired fasting glucose, prediabetes, voglibose, metformin, alpha glucosidase inhibitor, glycemic control, glycosylated hemoglobulin, fasting blood glucose, post prandial glucose

Introduction

Diabetes Mellitus (DM) is a chronic metabolic disorder which has affected worldwide people, and it has a major significant role in morbidity and mortality caused by its complication such as micro-vascular or macro-vascular, which eventually affects various vital organs [1]. It has been roughly estimated that by the year 2030, the diabetic population will rapidly be more than double i.e. from 21.7 million to 79.4 million in India. However, it is a fact that the prevalence rate of diabetes is far much more than this estimation of diabetic population, as many of the patients are asymptomatic and are unaware about diabetes as it goes undiagnosed for years till patient notices some major problem or frank symptoms. This is usually accounting for nearly another set of one-third of estimated cases [2].

Prediabetes is the state in which all the diagnostic criteria for diabetes are not met. It is the 'grey area' between normal blood sugar and diabetic levels. Various studies have shown that Prediabetes itself is associated with insulin resistance and there is increased risk for cardiovascular disease.

Now ADA has clearly defined IFG (Impaired fasting Glucose) as FBG levels of 100 to 125 mg/dL, and IGT (Impaired glucose tolerance) as two-hour glucose levels of 140 to 199 mg/dL on the 75-g oral glucose tolerance test [3-4].

It is well established that anti-hypoglycaemic action of voglibose results from a reversible inhibition of membrane bound intestines α glycosidase hydrolyze enzymes which hydrolyze oligosaccharides and disaccharides to glucose and other monosaccharide's in the brush border of the small intestine. Thus, voglibose causes delay in the absorption and also digestion of various dietary polysaccharides by reversibly inhibiting carbohydrate digestive enzymes like sucrose, maltose, etc. This results in a better reduction in PPHG [5-7].

Methods

In the present study a total of 150 prediabetic patients were selected out of which only 100 participants were eligible for study. This study was an observational study comprising of two groups one group received medication i.e. voglibose apart from diet and life style modification and other group was a placebo group in which patients were kept on diet and life style modification only.
Inclusion Criteria: 1) Age: 20-60yrs, 2) FBS: 101-125mg/dl, PPBS: 141 -199mg/dl, 3) BMI: 24-29 4) HbA1c: 5.7-6.4%.

Exclusion Criteria: 1) Known Diabetic 2) Any h/o of intake of oral Hypoglycemic Agents 3) Preexisting CAD, Renal Dysfunction, Hepatic Dysfunction, Gastro-intestinal Disorders.

Results

100 eligible patients were enrolled as per Inclusion criteria, they were divided into two groups, Group 1 (n=53) was placed on Diet, lifestyle modification and Voglibose 0.3mg twice a day, whereas the Group B (n=47) was placebo group. The mean duration of treatment was 24·6 weeks (SD 18.4)—i.e.23.6 weeks (17·5) for voglibose and 25·4 weeks (18.9) for placebo. In group A (n=53), there were 23 males (43.39%), and 30 female subjects (56.60%), whereas in the placebo arm (n=47), there were 20 males (42.55%), 27 Female (57.44%). In the analysis, we found that patients on voglibose was better and the glycemic control was within the standard recommended lines than placebo in individuals treated for an average of 23.6 weeks. Patients treated with voglibose had a lower risk of progression to type 2 diabetes than did those on placebo. Patients were monitored for the complete duration of study, and the impact of voglibose on Glycemic level was monitored.

Discussion

Voglibose is α glucosidase inhibitor; usage of it is prevalent Asian countries due to multiple dietary habits. We have shown that addition of voglibose in patient with prediabetes helps in achieving better glycemic control and these patients have lower incidence of complication over period of time will be less [6-9].

A study was done by Chiasson JL et.al in 2002, to prevent non-insulin dependent diabetes mellitus (to stop NIDDM) in patient with IGT. These who were treated with α-glycosidase inhibitor and it have shown there is significant reduction of PPHG. It has also shown, there is significant reduction in the risk of progression to frank DM, but the study has also shown that there is 34% risk reduction in development of new cases of hypertension and also there is 49% risk reduction in CVD [10-11].

The recent placebo-controlled prospective STOP-noninsulin-dependent diabetes mellitus (STOP-NIDDM) trial have demonstrated that acarbose 100mg three times daily had significantly reduced the risk of developing type 2 diabetes in patients with IGT [11]. The 6-year Early Diabetes Intervention Trial (EDIT), had compared the effect of acarbose 50mg thrice daily to metformin, it has showed a trend of positive effect of acarbose when compared to placebo, in a mid-term 3-year analysis, which should be confirmed in the final analysis.

Conclusion

Voglibose has emerged as a popular alternative to metformin for the management of prediabetes in the Indian population. Further, randomized cross trials and large population based studies are required. The limited small study has shown significant reduction of glycemic level in prediabetic patients.

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