ACARBOSE IN TYPE 1 DIABETES MELLITUS

M. K. Sharma*, K. Sukhdev**

ABSTRACT

Alpha glucosidase inhibitor, acarbose, is a new addition for diabetes therapy. Recently there have been few reports of acarbose efficacy in type 1 diabetics also. The objective of our study was to test the effect of acarbose on glycemic control of type 1 diabetic patients, when given with lunch. A total number of 20 subjects were tested. They all ate 3 major meals, two meals were managed with insulin (i.e. breakfast and dinner) and acarbose was given at lunch. In 10 patients (i.e. the control group), insulin was given at breakfast, lunch and dinner. All patients were studied for one and a half years for metabolic control, weight gain and quality of life measures.

In this study, the patients on acarbose along with adequate amounts of insulin had similar metabolic control as compared to patients on 3 doses of insulin. Fasting glucose, PPBS, HbA1c, weight gain and general well being were similar. There was no significant hypoglycemia in the study subjects. The use of acarbose was not associated with any major side effects.

KEY WORDS : Type 1 diabetes; Acarbose.

MATERIAL AND METHODS

We recruited 20 patients with type 1 diabetes mellitus (DM) from our diabetic clinic. The diagnosis of type 1 DM was based on clinical history and the finding of high plasma glucose concentration and presence of ketones in the urine. The subjects were explained about the study in detail and a written informed consent was taken from them. 10 patients were ready to try the therapy and were taken for the study. 10 patients were taken as controls. We randomly allocated 20 patients of type 1 DM, between 10 to 14 yrs to the study group, with equal M:F ratio. Their height and weight were measured. All the patients were monitored with fasting, post prandial blood sugar, HbA1c and micral test.

Group I received short acting insulin with breakfast and lunch, and a combination of short acting and long acting insulin at dinner, whereas group II was given a combination of short acting and long acting insulin at breakfast and dinner and acarbose (1-3 mg/kg of body wt.) at lunch. All patients of group II were instructed to eat their lunch between 3-5 hrs of breakfast, coinciding with the time of peak action of the long acting insulin.

The patients were followed at 3 monthly intervals for 18 months. Each time their fasting, PPBS and HbA1c were measured in a standard laboratory. In between, every patient was asked to do blood glucose estimation at home by a glucometer. Almost daily both fasting and post meal blood glucose was measured and dose of insulin was adjusted on the telephone. In the group II, dose of acarbose was also increased, if the post meal blood sugar was found to be more than 140 mg/dl. In a few patients, if the post meal blood glucose was not controlled by even 50 mg of acarbose, then the dose of long acting insulin was increased at breakfast. For the initial 2 months, SGPT was measured every 15 days to rule out drug-induced hepatitis. When it was seen that there is no change in the SGPT value, further measurement was not done and patients were asked to report if there was any anorexia.

Blood glucose was measured frequently at home and at our clinic with the help of a glucometer. The patients were instructed to go to a laboratory and get their blood sugar test every month by glucose oxidase method. HbA1c was measured at 3 months interval by turbidometric method. Urine examination was done frequently for measurement of ketones.

RESULTS

All the patients completed the study. No patient had any side effect of acarbose therapy. No patient had severe hypoglycemia or hyperglycemia, and no patient developed ketoacidosis in the observation period.

Table 1 shows baseline characteristics of both group I and group II and they were comparable in all regards. Before enrolling in the study, all the patients had poor metabolic control. They were unaware of self-monitoring of blood glucose (SMBG). Extensive education regarding blood glucose monitoring and treatment was done, which took almost 8-10 hours per patient over various consultations. Fig. 1, 2, 3 and 4 shows that initially metabolic control was

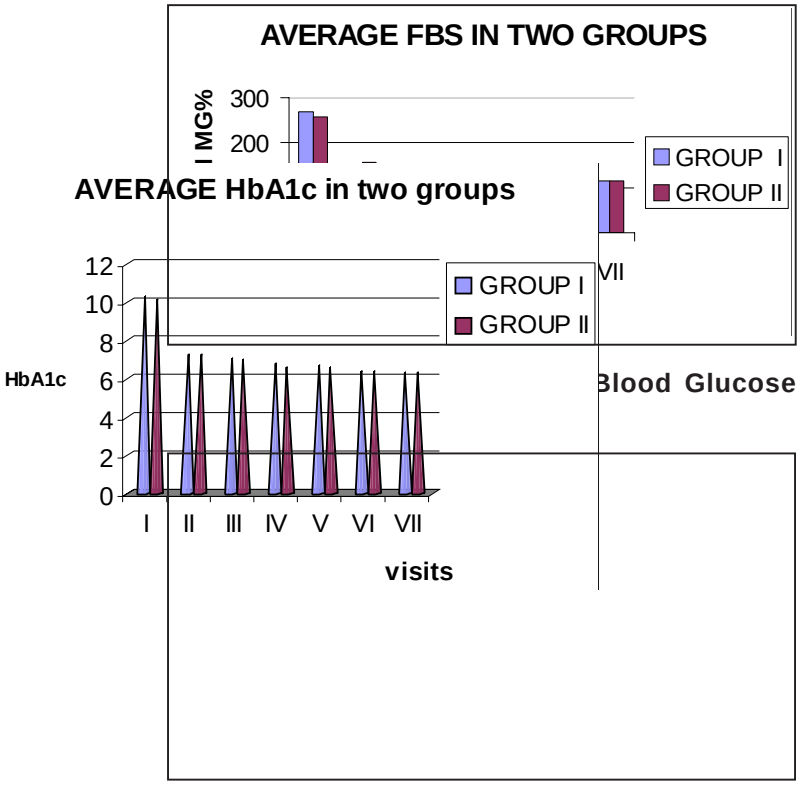
**Director, ** Assistant Director, CHL Apollo Hospital and Sharma Diabetes Clinic, 205, Vikram Tower, Agrawal Nagar, Indore (M.P), India.*

comparable in the 2 groups but the change in metabolic control was evident at the second visit i.e. after 3 months. The patients of group II had less PPBS but their fasting sugar remain unchanged. Also, the patients of group II required approximately 8-10 units of less insulin and achieved lesser HbA1c value, as compared to group I.

Table 1- Baseline Characteristics of Patients

CHARACTERSTICS	GROUP 1	GROUP II
Age (yrs.)	12.2 ±2	12.0 ±2
Sex (m:f)	5:5	5:5
Height (cm.)	146.75	144.42
Weight (kg)	35.85	35.1
FBS (mg %)	267	255.7
PPBS (mg %)	290.1	310.4
HbA1c	11.7	11.16

Fig. 1 - Average Fasting Blood Glucose Levels in the Two Groups



DISCUSSION

Insulin is the mainstay of treatment of type 1 DM and is irreplaceable in its treatment. But as the children of this age group are usually school going, one of three meals falls during school time, when in India it is not always practically possible to inject insulin. This study was conducted to know whether at the third meal acarbose can replace short acting insulin. As there should be no insulin deficiency at any time in type 1 diabetics, long acting insulin was prescribed at breakfast to cover up this period. Overall we saw that acarbose (1, 2) is very safe, effective and does not allow much weight gain, reduces insulin doses by about 8-10 units and gives better psychological satisfaction to the children as they do not have to inject insulin at school.

This was a short term study with small number of patients, but a large study of more than 100 patients with long term follow up is required to know the exact place of acarbose in the treatment of type 1 diabetes.

Fig. 3 - Average Insulin Requirement in the Two Groups

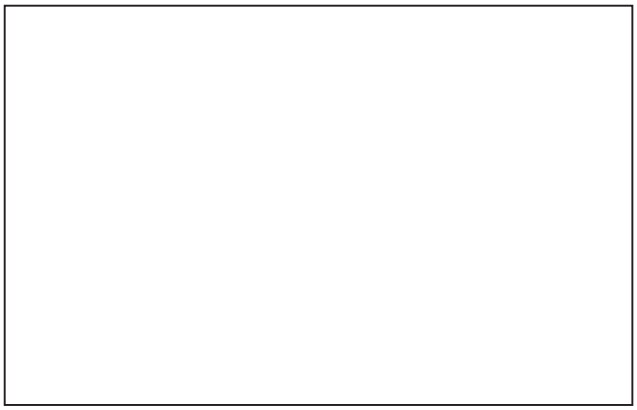


Fig. 4 - Average HbA1c in the Two Groups

REFERENCES

1. Hollander P, Pi-Sunyer X, Coniff RF. Acarbose in the treatment of type I diabetes. Diabetes Care, 1997; 20; 3; 248-53.

2. Hollander P. Safety profile of acarbose, an alpha glucosidase inhibitor. Drugs 1992; 44; Suppl 3: 47-53.