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LETTER TO THE EDITOR

EVALUATION OF THE EFFICACY OF BITTER GOURD (MOMORDICA CHARANTIA) AS AN ORAL HYPOGLYCEMIC AGENT – A RANDOMIZED CONTROLLED CLINICAL TRIAL

Sir,

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Momordica Charantia (bitter gourd) is one of the many plants considered to have a hypoglycemic effect and many diabetic subjects consume it because of its hypoglycemic effect (12). Studies done in animal model, mainly steptozotocin induced diabetic rats and mice have shown significant lowering of blood glucose levels (3–8). In some clinical trials momordica charantia is shown to have a beneficial effects in diabetic subjects (9, 10). This study was conducted to evaluate the usefulness of Momordica charantia in mild to moderate type 2 diabetes mellitus using a randomized controlled study design.

This study was conducted in a tertiary care 1800-bed teaching hospital in south India. Clearance was obtained from the Institutional Medical Ethics Committee for this study. Consecutive type 2 diabetic patients who attended the medical outpatients with fasting plasma glucose (FBS) of 140–200 mg/dl and post prandial plasma glucose (PPS) of 200–300 mg/dl were recruited to the study. Patients were excluded if they were diagnosed to have type 1 diabetes mellitus or had FBS >200 mg/dl and PPS >300 mg/dl. Diabetic patients with infection or with diabetic related complications, Pregnant women, lactating mothers and patients on insulin for sugar control were also excluded from the study. Sample size was calculated to get a 30 mg/dl reduction in FBS/PPS, keeping alpha error at 5% level and beta error at 10% level, 25 patients were required to be recruited in each arm.

Patients were randomized to receive either bitter gourd tablets (26 subjects) or placebo (24 subjects). The bitter gourd tablets were made from shade dried powdered fresh whole fruit. The average sized fruit weights around 5 gm when dried. Each tablet contained 1 gm of dried fruit and each patient received 2 tablets thrice daily, after meals. Riboflavin was given as placebo, as placebo identical to BG could not be made and riboflavin is not known to have any hypoglycemic effect and it is freely available. All patients were asked to continue their routine anti diabetic treatment, which included dietary modification and oral hypoglycemic agents such as sulfonylureas and biguanides.

Initial screening included routine blood and urine tests including FBS/PPS. Glycemic control was assessed by fructosamine assay since it has an advantage over HbA1C in assessing the short-term glycemic control (2 to 3 weeks). At the end of 2 and 4 weeks, FBS/PPS and fructosamine assays were repeated. Patients were instructed to bring all the left over medicines on follow-up to ensure compliance. As the tablets were dissimilar, the investigator could not be

blinded, the patients and laboratory personnel were blinded. Comparison of FBS/ PPS and fructosamine assays at 2 and 4 weeks was done by analysis of variance (ANOVA) for repeated measures.

The baseline characteristics, (Table I) Mean age and sex distribution was similar in both the groups and female subjects were more in both the groups. The mean values of FBS, PPS and fructosamine after 2 and 4 weeks (Table II) showed no significant change. Mean decline in plasma sugars and serum fructosamine over time also showed no significant charges. None of the patients noticed any side effects with bitter gourd such as gastrointestinal disturbances or allergic skin manifestations.

TABLE I: Baseline characteristics of the recruited the subjects.

	Treatment group	*Placebo group*
Numer	26	24
Males	7	9
Females	19	15
Mean age ± SD Males	52.3±10.9	57.6±7.6
Mean age ± SD Females	52.2±6.2	50.9±10.8
Lost to follow up	3	5

SD = standard deviation

TABLE II: Comparison of the follow up data, plasma glucose and Fructosamine values at base line, two and four weeks in the treatment and placebo group.

	Treatment group (n26)	*Placebo group (n24)*
Number of subjects Followed up		
At 2 weeks	23	17
At 4 weeks	22	19
FBS value		
At base line	150.1±26.9	155.8±25.0
At 2 weeks	151.2±38	168.5±32.9
At 4 weeks	150.0±35.3	150.7±35.4
P value	NS	NS
PPS value		
At base line	264.4±32.8	253.8±29.4
At 2 weeks	226.9±57.6	261.9±30.3
At 4 weeks	230.4±61.2	257.6±62.9
P value	NS	NS
Fructosamine value		
At base line	350.8±56.8	349.1±62.0
At 2 weeks	321.4±47.6	324.0±49.9
At 4 weeks	319.1±60.7	333.9±64.1
P value	NS	NS

ND = Not significant statistically, FBS = Fasting blood sugar, PPS = Post prandial blood sugar.

The hypoglycaemic effect of bitter guard is said to be mediated through an insulin secretogenic effect or through an influence on enzymes involved in glucose metabolism (11). It is suggested that viable beta-cells capable of secreting insulin is required for Momordica charantia to exert its oral hypoglycemic activity (12) and in animal model it is noted that the number of beta cells increases among those treated with Momordica charantia (13). Some studies have noted improvement in glucose tolerance with out any significant alteration in plasma insulin level suggesting that Momordica charantia may also have an extrapancreatic effect (2). Acetone extracts from whole fruits powder of BG has been shown to lower blood sugar in alloxan diabetic rats (5). In an another study on experimentally induced diabetic rat's, freeze dried bitter gourd powder did not show any beneficial hypoglycemic influence in terms of reducing the blood glucose level or on the excretion of diabetes related metabolites (1). In some uncontrolled trials administration of Momordica charantia in diabetic subjects either as aqueous homogenized suspension of the vegetable pulp or as fruit juice have shown a significant improvement in glucose tolerance (9, 10).

The present study showed no significant change in blood sugars or fructosamine levels in either treatment or placebo group. The mean drop in blood sugars and serum fructosamine levels in both groups over time

was also not significant. Though decreased levels of riboflavin is noted to occur among patients with type 2 diabetes (14) administration of this as a placebo, in the placebo treated patients in this study unlikely would have had any hypoglycemic effect. There could be many reasons for the insignificant change in blood sugar levels. Bitter gourd may not have hypoglycemic effect, larger quantity of the drug may have to be ingested, drying the fruit or actual making of the tablets may have affected the efficacy of bitter gourd. The hypoglycemic effect of the plant may be reassessed using the raw fruit or by a different method of extraction of its constituents. We conclude that dried whole fruit of Bitter Gourd has no blood sugar lowering effect, when administered at the dose that was used in this study.

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