ORIGINAL RESEARCH PAPER

Diabetology

KEY WORDS: Momordica Charantia, Taste Good Biscuits, Type 2 Diabetes Mellitus, Continuous glucose monitoring system.

EVALUATION OF THE EFFECT OF TASTE GOOD BISCUITS ON BLOOD GLUCOSE LEVELS IN PATIENTS WITH TYPE 2 DIABETES MELLITUS

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ABSTRACT

BACKGROUND: Momordica charantia is widely used in the traditional medicine to manage patients with type 2 Diabetes Mellitus(DM). **OBJECTIVE:** To evaluate the effect of Taste Good biscuits (TGB) on blood glucose levels in patients with type 2 DM using CGMS. **MATERIALS AND METHODS:** This was an open label, controlled, non-randomized, prospective study. Total duration of study was for 14 days, 1-7 days of control period without TGB and 8-14 days of active period with TGB. During the control period regular antidiabetic treatment was continued, however during the active period, two TGB were consumed at 11am and at 4pm along with their regular anti diabetic treatment. Continuous glucose monitoring system (CGMS) was used to detect the fluctuations in the blood glucose levels during the entire study period. **RESULTS:** 62 type 2 DM patients participated in the study, 3 were lost to follow up. 39 were males and 20 females. There was statistically significant reduction in the mean glucose values during the active period with TGB as compared to the control period without TGB ($p < 0.001$). The glucose variability between the minimum and maximum glucose during the control period was statistically significantly more as compared to active period ($p < 0.01$). The glucose levels were in the target range of (80-140mg/dl) during the active period as compared to the control period ($p < 0.001$). However, the glucose levels were above the target range during the control period as compared to the active period ($p < 0.001$). **CONCLUSION:** TGB reduced the glucose variability in patients with type 2DM, hence TGB can be used as an adjuvant with regular antidiabetic medications.

INTRODUCTION:

Diabetes mellitus(DM) is one of the major health condition all over the globe. In addition to the main stream allopathy treatment, 30% of the patients with DM use complementary and alternative system of medicine[1].

Momordica charantia (M.Charantia) is commonly used in the treatment of DM[1]. A number of proteins, peptides and bioactive compounds have been isolated from various parts of the plant. Anti-diabetic properties of the M.charantia have been consistently established in various clinical trials[2].

M. charantia is a rich source of vitamins, minerals, dietary fibre along with high anti-oxidant properties. Bitter gourd also contains Polypeptide-p or p-insulin, an insulin like hypoglycaemic agent. It reduces the blood sugar levels in the body by acting similarly to the human insulin apart from pancreatic rejuvenation. Charantin is the other bioactive compound with anti-diabetic properties[1].

M.Charantia has been shown to have protective effects on the target organs by delaying nephropathy, neuropathy, retinopathy, gastroparesis, cataract and atherosclerosis as well[3].

The broad spectrum antimicrobial activity of M.Charantia may protect patients with diabetes who are vulnerable and also non-diabetic individuals against disease causing organisms that are prevalent in areas where this vegetable is popular[3].

The concept of food as medicine is gaining popularity for treating the DM. M. charantia has been used as a dietary supplement and ethno-medicine throughout centuries for relieving symptoms and conditions related to DM[1]. Food quality and DM has a close association with one another[4].

With this concept Karela biscuits (Taste Good biscuits) have been developed by Azista Industries Pvt Ltd. as a mid meal snack. The glycaemic index is 57.93% with low glycaemic load of 6.14 per typical serving of two Taste Good Biscuits (TGB). These biscuits contain high fibre without having added sugars, transfat, and cholesterol[5].

Optimal glycaemic control in UKPDS[6] and ADVANCE[7] trials failed to prevent macro-vascular events and death. Glycaemic variability and quality of life have been added to the existing parameters of fasting blood glucose, post-prandial blood glucose and HbA1c[2].

Fluctuating blood glucose levels have been shown to have harmful effects on cardiovascular system than chronic hyperglycaemia. Hence, the new concept of glycaemic control i.e. glycaemic variability[8].

Continuous glucose monitoring system (CGMS) helps to detect the fluctuations in the blood glucose levels, which may not be evident on self monitoring blood glucose . CGMS helps patients to achieve their goal of optimum glycaemic control[9,10]. Ambulatory glucose profile sensor measures interstitial glucose. Interstitial glucose and plasma glucose were found to have good correlation similar to capillary glucose checked with glucometer and ambulatory glucose profile[11]. The present clinical study was to demonstrate the effect of TGB on reducing the glucose variability in patients with Type 2 DM using CGMS.

MATERIALS AND METHODS:

This was an open label, controlled, non – randomized prospective clinical study conducted at Kumudini Devi Diabetes Research Centre, Ramdevrao Hospital, Hyderabad. Patients with established diagnosis of Type 2 DM irrespective of their anti-diabetic treatment being taken and willing to participate in the clinical study after explaining the study procedure were included in the study after obtaining their written informed consent.

At baseline the demographic data (Age, gender, height, weight, BMI), vitals and duration of DM along with treatment details were recorded.

The total duration of study was for 14 days. It includes 1 to 7

days of control period without TGB and 8-14 days of active period with TGB. On day 1, a tiny electrode called glucose sensor was inserted under the skin using insertion device to the back of the patient's upper arm. A self adhesive pad held the water resistant disposable sensor in place for 14 days. The sensor continuously measures glucose through a small filament every 15 minutes for 14 days. For the first 7 days (control period) the patients were taking their regular anti-diabetic treatment. On day 8, the patients reported in the department and TGB were dispensed to the patients to be consumed 2 biscuits at 11 am and again 2 biscuits at 4 pm in the evening for 7 days as mid meal snack (day 8 – 14 (active period)) along with their regular anti diabetic treatment. On day 15, patients reported back in the department, Free style Libre Pro reader was used to scan the sensor and download the 14 days' glucose results stored in the sensor. The data was uploaded using the device software to generate summary glucose reports.

Patients were considered clinically evaluable if they have met all the baseline and end of the study criteria and have received study product for the entire duration of the study period. Development of any undesirable effects, during the study period were recorded. The compliance was calculated by the TGB packet count on day 15.

Statistical analysis was performed using two sided testing for all statistical deductions and the statistical significance level was $p<0.05$. Standard summary statistics (arithmetic mean and standard deviation) were calculated for all quantitative variables. Efficacy analyses was based on the full analysis of data set including all patients who received study product and having complete measurements of blood glucose during the entire study period. To check the normality of the data "Kolmogorov Smirnov test" was used. For all the continuous variables, to compare the change from control period (without TGB) to the active period (with TGB) Paired 't' test was applied. Safety variables were evaluated during the entire study period.

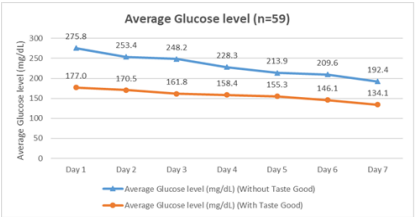
RESULTS:

Total 62 patients were enrolled into the study. Out of 62 patients, three patients were lost to follow up. Demographic data is available for 59 patients. Out of 59 patients 39 were males and 20 were females, the mean age was 49.3 ± 11.4years, mean weight, height and BMI was 69.8 ± 12.1 Kgs, 162.6±8.6 cm. and 26.5 ± 5.1 respectively.

In addition to DM, 18 patients had hypertension, 6 patients had thyroid dysfunction, one patient had coronary heart disease and one patient had psoriasis. The mean duration of DM was 7.78 ± 7.22 years. Forty-seven patients were on insulin and rest of them were on oral anti-diabetic treatment.

Figure 1 shows the average glucose values from day 1 to day 7 without the consumption of TGB (Control period) and day 8 to day 14 with the consumption of TGB (Active period).

Figure 1



There was statistically significant reduction in mean glucose values for the entire week with TGB (157.6 + 14.5 mg/dl) as compared to without TGB (231.7 + 29.0 mg/dl) ($p<0.001$).

The difference between the maximum glucose of 371 mg/dL and minimum glucose of 246 mg/dL was 125 mg/dL without TGB. Similarly, the difference between the maximum glucose 278 mg/dL and minimum glucose of 171 mg/dL with TGB was 107 mg/dL. The glucose variability between the minimum and maximum during control period (without TGB) was statistically significantly more as compared to active period (with TGB) ($p<0.01$) (Table 1)

Table 1: Comparison of mean glucose variation without and with TGB (mg/dL) (n=59)

Regular Treatment	Min	Max	Mean±S.D	Difference between Min & Max	P-Value
+Without TGB (Week 1)	246.0	371.0	311.9±41.8	125.0	<0.01
+With TGB (Week 2)	171.0	278.0	216.1±33.3	107.0	

Statistically significant percentage of the time the mean glucose levels were in the target range (80 – 140mg/dl) during active period as compared to the control period. ($p< 0.001$) (Table 2).

Table 2: Mean Time in Target Glucose Range (%) Week wise comparison (n = 59)

Regular Treatment + Without or With TGB	Min	Max	Grand Mean ± S.D	P-Value
Without TGB (Week 1)	6.4	23.8	13.9 ± 5.7	<0.001
With TGB (Week 2)	26.7	42.1	33.6 ± 5.5	

However, the mean glucose levels were above the target range during the control period as compared to the active period. This was statistically significant. ($p<0.001$) (Table 3)

Table 3: Mean Time Above Target Glucose Range (%) Week wise Comparison (n = 59)

Regular Treatment + Without or With TGB	Min	Max	Grand Mean ± S.D	P-Value
Without TGB (Week 1)	71.9	92.6	83.5 ± 6.9	<0.001
With TGB (Week 2)	41.0	65.8	55.9 ± 8.9	

Compliance was > 85 % and none of patients were withdrawn from the study due to undesirable effects. TGB were well tolerated.

DISCUSSION:

The complementary and alternate system of medicine is gaining the momentum with available knowledge of the active components present in the plants. Medicinal plants like M.Charantia is popularly used for its antidiabetic properties as it can be used as an adjuvant along with regular allopathic medicines[1].

Proper glycaemia control has been shown to reduce morbidities, which can be achieved by striking a balance between nutrition, physical activity, medication, and psychosocial factors[12].

M.Charantia may be the feasible option for ethnic minorities who have a high prevalence of diabetes but preferred treatment based on natural products according to their cultural beliefs[1]. Application of bitter melon in food and pharmaceutical fields are still in the initial stages and the health benefits are far from being fully utilized. Because of its numerous health benefits, the plant can be utilized in lowering blood glucose and various other conditions with broad prospects under the premise of ensuring safety[2].

Relevant products of M. charantia are quite popular like bitter gourd tea, known as gohyah made from dried slices, is used mainly for medicinal purposes. With further research on bitter gourd, the relationship between structure and mechanisms of the efficacy of the various functional constituents will be clarified. As it is important to address certain gaps and contribute to build up the evidence on M. charantia and recommend it as an adjuvant therapy in the management of type 2 DM, this study was conducted to provide quality nutritive, more accessible and flexible mid meal snack[3].

Conclusion: TGB can be used as an adjuvant therapy along with regular antidiabetic medications in patients with type 2 DM to reduce the glucose variability.

CONFLICTS OF INTEREST:

Authors declare no conflict of interest.

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