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CLINICAL EFFICACY AND SAFETY OF HOLY BASIL-BASED ANTI-DIABETIC TEA

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Abstract

The study was designed to formulate anti-diabetic herbal tea from natural holy basil leaves that contain sufficient nutrient for diabetic patients, and the major goal was to maintain the normal plasma glucose level for them. This study was carried out in two phases. In the first phase, Anti-diabetic tea was formulated by appropriate processing and blending of mainly holy basil (*Ocimum sanctum*) leaves, moringa (*Moringa oleifera*) leaves, ginger (*Zingiber officinale*) and stevia leaves. This recipe was standardized and evaluated for organoleptic acceptability by nine points hedonic scale. The overall acceptability score was 7.9 out of 9. In the second phase, 60 patients of type 2 diabetes mellitus were randomly selected for a three-month clinical trial. Both groups were age, and BMI (Body Mass Index) matched. At baseline study, no significant differences were found in the two selected groups, but after three months trial, the results showed plasma glucose level was significantly lowered ($p < 0.05$) in the intervention group. However, the hematological and liver function tests in both groups were in an acceptable range. Hence, the study acclaims that the regular intake of this holy basil-based anti-diabetic tea can maintain the plasma glucose level as close to normal level.

Keywords: Holy basil, Anti-diabetic tea, Type2 diabetes mellitus, Organoleptic taste, Plasma glucose

Introduction

Diabetes mellitus (DM) is one of the most prominent public health concern, affecting 285 million people in the world at 2010, with type 2 making up about 90% of the cases (Williams, 2012). Its incidence is increasing rapidly, and by 2030, this number is estimated to almost double because of the rising prevalence- predominantly of non-insulin dependent diabetes mellitus (type 2 diabetes) especially in the South East Asia and Asia-Pacific region (Wild *et al.,* 2000).

In terms of absolute numbers of individuals with diabetes, India, Pakistan and Bangladesh make up three of the top ten countries globally and together with the region with the highest

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number of diabetes-related deaths currently (Wild *et al.,* 2000 and IDF, 2009). According to the WHO report, Bangladesh had 3.2 million diabetic subjects in 2000, and the number is expected to increase to 11.1 million by 2030 (WHO, 2006). A recent population-based study showed a significant increase in the prevalence of DM in rural Bangladesh, from 2.3% to 6.8% over 5 years (Rahim *et al.,* 2018). This prevalence was higher than found in the previous rural-based studies on the same population (Rahim *et al.,* 2008; Sayeed *et al.,* 2003). These several small-scale population-based studies provide an increasing trend of diabetes prevalence in rural and urban communities in Bangladesh (Rahim *et al.,* 2018; Sayeed *et al.,* 2003; Hussain *et al.,* 2007; Akhter *et al.,* 2011).

Normal plasma glucose level (fasting adult) is below 110mg/dl. Generally a high plasma glucose level in fasting stage is ≥ 126 mg/dl and in 2-hours postprandial stage is ≥ 200 mg/dl (WHO, 2006). A major goal in controlling diabetes is to keep plasma glucose levels as close to the desired range as possible.

Diabetes causes substantial morbidity, mortality, and long term complications and remains a significant risk factor for cardiovascular diseases (Ali *et al.,* 2011; Yusuf *et al.,* 2004). Type 2 DM has a distinctive association with cardiovascular diseases (CVD), the relative risk of developing coronary diseases is 2 to 4 times higher in diabetic patients compared to non-diabetic persons (Gupta *et al.,* 2008). Moreover, CVD accounts for an overwhelming 65 to75% of deaths in people with diabetes (Moss *et al.,* 1991). But the considerable advancement has been made in the management of diabetes and its complications in recent years (Tatti *et al.,* 2010). Despite the fact that the improved understanding of its pathogenesis and the identification of the various risk factors, prevention of the disease and its complications are still challenging. Traditionally, Type 2 DM has been controlled with dietary modification, regular exercise, herbal medicine, oral hypoglycemic drugs, etc. (Yosef, 2014). However, these have remained the main contributors to oral hypoglycemic treatment for more than 50 years (Rahim *et al.,* 2010).

The therapeutic management of diabetes in Bangladesh still suffers from various limitations. A lot of local plant materials have been used for the treatment of diabetes for centuries with reputed benefits in diabetes (Toshio, 2007; Rahmatullah *et al.,* 2010). Therefore, a scientific evaluation of these plant materials has been an important responsibility for the scientists and also a logical way of screening for new anti-diabetic herbal products.

Bangladesh has a tremendous wealth of medicinal plants, and different study has shown that it has fabulous effect on different diseases such as heart disease, liver diseases, kidney diseases, cardiovascular, diabetics, obesity and so on (Kadir *et al.,* 2012; Toshio, 2007 and Rahmatullah *et al.,* 2010). The consumption of herbal medicine will get the immense benefit for ensuring their sound health (Yosef, 2014; John, 1997). Holy basil (*Ocimum sanctum*) is scared as ‘queen of herbs' in the Indian subcontinent. It is

considered as an adaptogenic and balancing different process in the body. Traditionally in Ayurveda Medicine, it is believed as promoting longevity ‘elixir of life'. Hypoglycemic effects were found in animal studies (Chattopadhhay, 1993). A clinical controlled trial of holy basil (n = 40) showed positive effects on both fasting and postprandial glucose in patients with Type 2 diabetes using a local preparation of fresh leaf powder mixed in water for 4 weeks and no adverse effects were observed (Agarwal, 1996).

In this perspective, an attempt has been made to formulate the anti-diabetic herbal tea by utilizing several natural plant materials. The main ingredient was holy basil leaves, besides this, each sachet (1g) of blended herbal tea contains a minute amount of moringa (*Moringa olicifera*), ginger *(Zingiber officinale)* and stevia leaves. The main objective of this study was to evaluate the effectiveness of this formulated herbal anti-diabetic tea on T2DM patients for controlling plasma glucose level.

Materials and Methods

The study was carried out in two phases.

First Phase

Anti-diabetic herbal tea was formulated by the guarded secret ratio of several natural plant materials including holy basil leaves as a major ingredient and standardized organoleptic test by nine-point hedonic scale. The product was formulated in the research laboratories in Rigs Herbs, Dhaka Bangladesh. The product quality checked and toxicity tests were done in Chittagong Laboratories, Bangladesh Council of Scientific and Industrial Research (BCSIR). The color, flavor, appearance, granularity, and overall acceptability were evaluated.

Second Phase

A randomized, single-blind placebo-controlled clinical trial was conducted in a renowned diabetic hospital in Bangladesh (Bangladesh Institute of Research and Rehabilitation in Diabetes, Endocrine, and Metabolic Disorders, BIRDEM). All subjects in the treatment group were taken 2 sachets of prepared anti-diabetic herbal tea per day for 3 months. All subjects were taken 2 sachets blank herbal tea (normal tea) per day for 3 months. Ethical consideration was applied in this study design. If any Type 2 DM patient falls very sick and/or very high rise of blood glucose level or any other complexities detected, then it was treated with necessary drugs.

Inclusion criteria

Only patients fulfilling the following criteria were included in the study:

- Aged between 40 to 60 years
- No gender bias (both male and female)

- Patients diagnosed as type II diabetes with FBG > 120 mg\dl
- Patients who have given written informed consent

Exclusion criteria

- All type-II patients on insulin treatment
- High blood pressure (recognized)
- Obesity (BMI > 30)
- Type-I diabetes
- Presence of debilitating illness

Background information

Subject's name, age, sex, weight, and height were recorded, and blood pressure was taken routinely, along with BMI calculation. Moreover, polyuria, polydipsia, polyphagia, numbness, fatigue, and other diabetic complications presence or absence were noted as the medical history of the patients in the medical history.

Statistics

Data analysis was done with the aid of the SPSS statistical software version 16. The statistical analysis of the observed data at baseline and after three months was performed using independent and paired Student's t-test with significant, accepted values of $p < 0.05$.

Results and Discussion

Sensory evaluation of the anti-diabetic tea

Organoleptic test of the formulated anti-diabetic herbal tea depends on its first appearance, color, flavor & smell, texture and granularity, and overall test acceptability of the sample. Table 1 shows the nine-point hedonic scale scores and acceptability based on test members likings and dis-likings of their sensory evaluation. The overall acceptability of the formulated anti-diabetic herbal tea was acceptable, and the hedonic scale point was found to be 7.90.

Socio-demographic characteristics

Table 2 shows the socio-demographic and background characteristics of all subjects at base-line observation. Out of the 60 patients, the majority (83.4%) fell within 45 to 54 years. Again, the statistical summary shows the age, weight, height, BMI, and the duration of diabetes occurred for intervention, and control groups were very similar. The mean ages were 48.9 and 49.7 years, respectively, for the intervention and control groups, and this data shows no significant differences ($p > 0.05$) in the age distribution, i.e., age matched. Similarly, their mean weight, height, and BMI showed no significant differences ($p > 0.05$) in both groups.

Table 1. Organoleptic acceptability of the formulated anti-diabetic herbal tea.

Quality Factors	Hedonic scale	
	Points	Results
Appearance	7.81	Like Moderate
Color	8.36	Like very much
Flavor	7.54	Like Moderate
Texture and granularity	7.32	Like Moderate
Overall acceptability	7.90	Acceptable

Table 2. Background characteristics of selected subjects in both groups at baseline

Variables	Intervention Group n (%)	Control Group n (%)	Total n (%)
Age (Years)			
40-44	3 (10.0)	2 (6.7)	5 (8.3)
45- 49	12 (40.0)	13 (43.3)	25 (41.7)
50-54	13 (43.3)	12 (40.0)	25 (41.7)
55-≥ 60	2 (6.7)	3 (10.0)	5 (8.3)
Sex			
Male	17 (56.7)	18 (60.0)	35 (58.4)
Female	13 (43.3)	12 (40.0)	25 (41.6)
	Mean ± SD	Mean ± SD	*P* Value
Age (Years)	48.9 ± 3.8	49.7 ± 4.2	0.41
Weight (Kg)	64.7 ± 4.5	66.5 ± 5.4	0.49
Height (cm)	163.6 ± 7.5	164.5 ± 8.1	0.38
BMI	24.1 ±2.9	24.5 ± 3.3	0.44
Mean duration of diabetes (Years)	8.1 ±1.8	8.4 ±2.2	0.39

Observation of clinical trials

Table 3 shows the subject's health conditions and complaints about common sign-symptoms of type 2 DM among intervention group and the control group before and after trial. The pattern of complaints after three months shows that there was a marked health conditions improvement in patients treated with anti-diabetic tea. Intervention with anti-diabetic tea relieved polyuria, polyphagia, polydipsia, fatigue, and lethargy in almost all cases significantly in the intervention group, whereas in the control group those were remained as before.

Table 3. Comparison of the subject's health conditions and complains about common sign-symptoms of diabetes mellitus

Responses	Intervention Group, n (%)			Control Group, n (%)		
	Base-line	After Trial	p-value	Base-line	After Trial	p-value
Polyurea	25 (83.3)	2 (6.7)	0.012	26 (86.6)	24 (80.0)	0.634
polydipsia	22 (73.3)	4 (13.3)	0.017	24 (80.0)	23 (76.7)	0.491
Polyphagia	24 (80.0)	4 (13.3)	0.014	22 (73.3)	21 (70.0)	0.576
Fatigue and lethargy	17 (56.7)	3 (10)	0.024	21 (70.0)	19 (63.3)	0.872

Fasting plasma glucose level monitoring

The severity of diabetes was usually determined by the fasting plasma glucose (FPG) and /or 2-hours postprandial plasma glucose levels. Fig. 1 shows the comparison of the fasting glucose level in baseline and after trial for both groups. At the base-line observation study (at day zero), the FPG level in the intervention group and control group all patients fell into the higher level (> 126 mg/dl). After three months of trial, there were no noticeably changes in the control group, only 20% of the patients fell into 110 to 125 mg/dl range.

On the other hand, significant changes were observed in the case of the intervention group. About one-third of patients had their plasma glucose level under normal controlled range (below 110 mg/dl), and 53.3% were under intermediate control, and only 13.3 % were at a higher level. Table 4 shows the average fasting glucose level in both groups. In the intervention group at the baseline study, it was 149 ± 22 mg/dl, which decreased significantly ($p < 0.05$) to 124 ± 31 mg/dl after three months of trial. On the other hand, FPG level in control group at the beginning of the study was 153 ± 25 mg/dl, which insignificantly ($p > 0.05$) decreased to 147 ± 26 after three months of trial.

Two-hour postprandial plasma glucose level monitoring

2-hour post prandial plasma glucose level also indicates the good criterion for diagnosis Type 2 DM. Fig. 2 shows the comparison of that diagnostic value in both groups before and after trial. At the baseline may only subjects in both groups fell into the higher level (> 200 mg/dl). After three months of trial, there were significant changes observed in the case of the intervention group. About 40% percent of their plasma glucose level was found under normal controlled range (below 140 mg/dl) and 53.3% were found under intermediate controlled range (140 - 199 mg/dl). The average 2-hours postprandial glucose level in the intervention group at the baseline study was 237 ± 31 mg/dl, which decreased significantly ($p < 0.05$) to 167 ± 37 mg/dl after three months of trial but in control group it was not significantly ($p > 0.05$) lowered after three months of trial (Table 4).

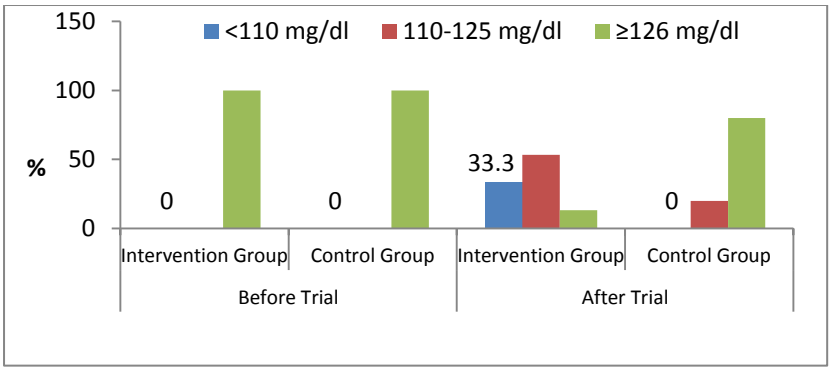

Fig. 1. Comparison of Fasting Plasma Glucose Level

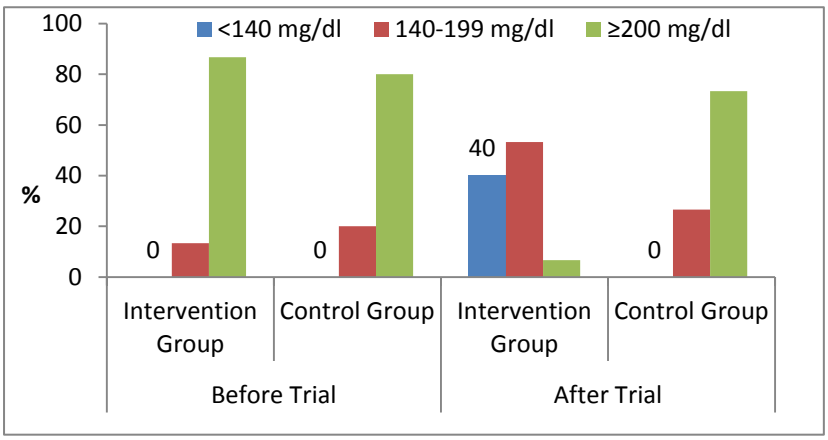

Fig. 2. Comparison of 2-h Post Prandial Plasma Glucose Level

Table 4. Comparison of the plasma glucose level at baseline and after a trial in both groups

Plasma glucose level (mg/dl)	Intervention Group (Mean ± SD)			Control Group (Mean ± SD)		
	Base-line	After Trial	p-value	Base-line	After Trial	p-value
Fasting plasma glucose	149 ± 22	124 ± 31	0.026	153 ± 25	147 ± 26	0.334
2-hours post prandial glucose	237 ± 31	167 ± 37	0.007	245 ± 36	239 ± 33	0.391

Lipid and hematological profile

Table 5 shows the distribution of the lipid profile and other essential hematological values before starting (at day zero) and after three months intervention of total of sixty individuals in both intervention and control group. Triglycerides and total cholesterol were slightly elevated in the control group, whereas they were lowered in the intervention group ($p = 0.074$) treated with anti-diabetic tea. Table 5 also shows the hematological and liver function tests were found to be within the normal levels in both the control and intervening groups, except slightly higher value in ESR and slightly lower in Hb level.

Table 5. Blood parameters comparison of the lipid profile and other laboratory tests at baseline and after a trial in both groups

Blood parameters	Intervention Group (Mean ± SD)			Control Group (Mean ± SD)		
	Base-line	After Trial	p-value	Base-line	After Trial	p-value
LDL (mg/dl)	155 ± 34	142 ± 39	0.135	147 ±39	151 ± 46	0.913
HDL (mg/dl)	52 ± 21	47 ± 17	0.271	49 ± 26	46 ± 23	0.329
Total cholesterol (mg/dl)	227 ± 45	199 ± 42	0.061	218 ± 38	223 ± 46	0.445
Triglycerides (mg/dl)	172 ± 35	147 ± 32	0.074	179 ± 38	182 ± 36	0.472
ESR	25 ± 13	26 ± 15	0.955	23 ± 15	19 ± 12	0.902
Hb (mg/dl)	10.9 ± 1.1	10.7 ± 1.4	0.726	10.7 ± 1.6	10.9 ± 1.7	0.792
HbA_1C (%)	8.7 ± 2.2	7.3 ± 1.7	0.001	8.9 ± 1.8	9.1 ± 2.1	0.526
SGPT (U/L)	17 ± 8	13 ± 9	0.001	19 ± 8	22 ± 9	0.227

The average HbA_1C level in the intervention group at the beginning of the study was 8.7±2.2%, which decreased significantly ($p < 0.001$) to 7.3 ± 1.7% after three months of trial. The average HbA_1C level in the control group at the beginning of the study was 8.9 ± 1.8%, which slightly increased but not significant ($p = 0.526$). Anti-diabetic herbal tea intervention also significantly lowered blood levels of SGPT.

Conclusion

The current study shows that formulated anti-diabetic tea intervention has a beneficial effect in reducing plasma glucose level in Type 2 DM patients. A slight but non-significant decrease in lipid profiles in patients of the intervention group was found. Also, no noticeable side-effects of the intervention were reported during the study, and there were no changes in therapy or intervention in either group. At the end of the study, many of the intervention group patients wished to continue the same anti-diabetic herbal tea regularly. The results have been impressive in favor of that formulated anti-diabetic tea. However, the study still leaves room for speculation as to whether the effect of anti-diabetic tea is additive or synergistic to other diet and lifestyle.

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