ORIGINAL ARTICLE

A Pilot Study Evaluating the Effects of Diabetes Specific Nutrition Supplement and Lifestyle Intervention on Glycemic Control in Overweight and Obese Asian Indian Adults with Type 2 Diabetes Mellitus

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Abstract

Background and Objectives: Medical nutrition therapy plays a crucial role achievement of optimal glycemic control in individuals with diabetes. This study aims to evaluate the effects of diabetes specific nutrition supplement (DSNS) along with lifestyle intervention in overweight and obese adults with Type 2 Diabetes Mellitus (T2DM).

Methods: A total of 120 overweight or obese individuals aged 30 – 65 years with T2DM, were randomly allocated to intervention (IG, n=60) and control (CG, n=60) groups in this 12-week study. All participants received dietary counselling with diet chart of 1400 kcal/day and recommendations for physical activity. DSNS was included in the dietary regimen adjusted within the daily calorie recommendations for intervention group. All participants were followed up monthly for anthropometric, biochemical and clinical assessments. Continuous glucose monitoring was performed during the initial 2 weeks and last 2 weeks of the study in a sub- sample using Flash Glucose Monitoring device to study glycemic excursions. Data was analyzed for the differences between intervention vs. control group using linear models.

Results: Compared to the control group, the intervention group showed significant reduction in glycosylated haemoglobin (IG: -0.95% *vs.* CG: -0.48%; p=0.020) and fasting blood glucose (IG: -18.47 mg/dL *vs.* CG: 1.34mg/dL; p=0.03) as well as a greater reduction in postprandial plasma glucose (IG: -29.77mg/dL *vs.* CG: -2.64mg/dL; p=0.053). There was also a significant reduction from baseline in incremental Area under the Curve (iAUC) (p=0.01) in the intervention group (Δ -22 mg) compared to the control group (Δ -7.9 mg) with a corresponding reduction in the Mean Amplitude of Glycemic Excursion (MAGE) (P=0.04). There was no difference between groups in body weight, waist circumference, blood pressure, and lipid profile. None of the subjects in the study reported serious adverse events.

Conclusion: This pilot study showed that a diabetes specific nutritional supplement was useful in improving glycemic control and reducing glycemic response in overweight and obese Asian Indian adults with T2DM.

Introduction

Comprehensive glycemic management in diabetes involves modification of diet and lifestyle patterns, in addition to use of anti-diabetic pharmacotherapy.[1] Dietary alterations that limit hyperglycemia following a meal are particularly important in enabling patients to attain glycemic goals and prevent complications.[2] Weight reduction, a cornerstone of diabetes prevention and management, has been shown to be best achieved by means of dietary intervention.[3] Unfortunately, patients with diabetes continue to face challenges in initiating dietary modification and maintaining it in the long run.[4]

Foods with a low glycemic index are preferred in individuals with diabetes as they have clinically valuable impact on glycemic control.[5] Fiber and lactose are dietary constituents that tend to bring down glycemic response and have beneficial outcomes by lowering HbA1c and PPG levels.[6] Data on the ideal total dietary fat content for people with diabetes are inconclusive, although an eating plan rich in monounsaturated and polyunsaturated fats may be considered to improve glucose metabolism and lower CVD risk.[1]

To ensure dietary consistency in diabetic patients, it might be worthwhile to prescribe a ready-to-use formula or a Diabetic Specific Nutrition Supplement (DSNS), which plays a supplementary role to drug treatment to prevent striking blood-glucose excursions. DSNS are available globally and have been evaluated through clinical studies. As per a systematic review and meta-analysis assessing 23 clinical studies and comprising 784 participants, DSNS was found to significantly reduce postprandial blood glucose, peak blood glucose

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concentration, glucose area under the curve and glycosylated haemoglobin (HbA1C) when incorporated in the overall lifestyle management plan.[7]

While clinical practice guidelines help in standardization and improvement of the care of individuals with prediabetes and T2DM, a directional tool would support individualizing these interventions. Transcultural Diabetes Nutrition Algorithm (tDNA) is a therapeutic tool intended to foster implementation of lifestyle recommendations and to improve disease-related outcomes in common clinical settings. The algorithm and related education initiatives resulted from collaborative work performed by an international group of healthcare experts with the aim of: (1) reinforcing the importance of nutritional interventions in prediabetes and T2D treatment; (2) encouraging healthy eating habits and regular physical exercise; and (3) adapting tDNA for different regions of the world with culture specificities and preferences in mind.[8] For India, the international panel of expert healthcare professionals developed tDNA, which was specific and customized considering the regional variations and diversity of the country.[9]

Objectives

The primary objective was to compare the efficacy of customized dietary counseling with inclusion of DSNS and physical activity versus standard of medical care (dietary counseling and physical activity) on HbA1c of T2DM patients over a period of 90 days.

The secondary objectives were to compare the efficacy of DSNS with dietary counseling and physical activity versus standard of medical care on:

1. Fasting Plasma Glucose(FPG) and Postprandial Glucose PPG [assessed 90 minutes post breakfast],
2. Body weight, body mass index, waist circumference,
3. Lipid Profile [total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides] and 4. Quality of life as assessed using the tool Quality of Life Instrument for Indian Diabetes Patients (QOLID)
5. Changes in Ambulatory Glucose Profile using Flash Glucose Monitoring (FGM) System.
6. The satiety score in subjects after consuming the DSNS drink. (over a period of 90 days)

Materials and Methods

Study participants

This was a randomized, prospective, open-label, comparative, single center, investigator-initiated pilot study conducted in 120 overweight/obese patients with T2D. This was a Post-Marketing Nutrition Study in which sample size was based on practical rather than biometrical considerations. The study included overweight and obese? adults with T2D identified from the medical records of a tertiary care center for diabetes. The inclusion and exclusion criteria for study participants are given below:

Inclusion Criteria

Participants aged 30–65 years of either gender, diagnosed with T2D of at least 1 year duration, treated with stable doses of oral anti-diabetic drugs like metformin, sulfonylureas, thiazolidinediones, DPP-IV inhibitors, GLP-1 agonists for at least 3 months before screening, HbA1c from 7.0 to 10.0%, BMI of ≥23 kg/m^2 and <30 kg/m^2 as per the consensus statement for Asian Indians for overweight obesity.

Exclusion Criteria

Participants were excluded if, he/she had T1DM, was currently on injections, had stage 2 hypertension with ≥160/100 mmHg with complications, was receiving any diabetes-specific nutritional food supplement (not including multivitamin supplements [vitamin, calcium or D supplements or B complex supplements and B complex syrups]) within 15 days prior to study start or taking any herbal/ayurvedic/traditional preparation that could potentially affect blood glucose. Females who were nursing/pregnant/are of child-bearing potential and not practicing an acceptable method of birth control/or did not plan to continue using this method throughout the study and did not agree to submit to periodic pregnancy testing during participation in the trial were excluded. Participants on Oral Contraceptive (OC) pills were included only if they had been using them for at least 3 months prior to signing the informed consent. Participants who have evidence or history of clinically significant hematological, renal, endocrine, pulmonary, gastrointestinal, cardiovascular, hepatic, psychiatric, neurologic or allergic disease, e.g., hemoglobin ≤12 g/dL for males and ≤10 g/dL for females, platelets <100,000 cumm, WBC count <4000/μL or >14,000/μL, fasting (≥8 hours) blood glucose ≥270 mg/dL, fasting (≥12 hours) blood LDL-cholesterol ≥160 mg/dL, fasting (≥12 hours) blood TGs>500 mg/dL, previous history of diabetic ketoacidosis, peptic ulcer or endoscopy demonstrated gastritis or any significant gastrointestinal condition within past 6 months, current history or history within past 6 months of unstable angina, myocardial infarction, cerebrovascular accident, transient ischemic attack, stroke or any revascularization were excluded. Additionally, history of coronary artery bypasses graft or stent implantation, clinically significant peripheral vascular disease, or congestive heart failure (NYHA Classes II-IV),A 12-lead ECG demonstrating QTc ≥450 msec, impaired hepatic function –SGOT ≥3x ULN, SGPT ≥3x ULN, total bilirubin ≥1.50 x ULN in the past 1 year, history of jaundice in the past 1 year, serum creatinine ≥1.4 for women and ≥1.5 for men in the past 1 year, history of AIDS or HIV infection, history of severe diabetic neuropathy including autonomic neuropathy, gastroparesis or lower limb ulceration or amputation or evidence or history of diabetic complications with significant end organ damage, history of illicit drug or alcohol abuse within last 1 year were criteria for exclusion.

All participants were given complete details of the study including any risks and benefits of participating in the trial. Written informed consent was obtained from all the participants. The study received approval from the Institutional Ethics Committee of the Madras Diabetes Research Foundation. The study was registered in Clinical Trial Registry of India no CTRI/2015/04/005693.

Dietary Intervention

Eligible participants with BMI ≥23.0 – ≤26.9 kg/m^2 were advised to consume 1 serving (52g) of DSNS (Glucerna SR, Abbott Nutrition International, India) supplement mixed with 200mL of water either at lunch or dinner time while participants with BMI ≥27.0 – ≤30.0 kg/

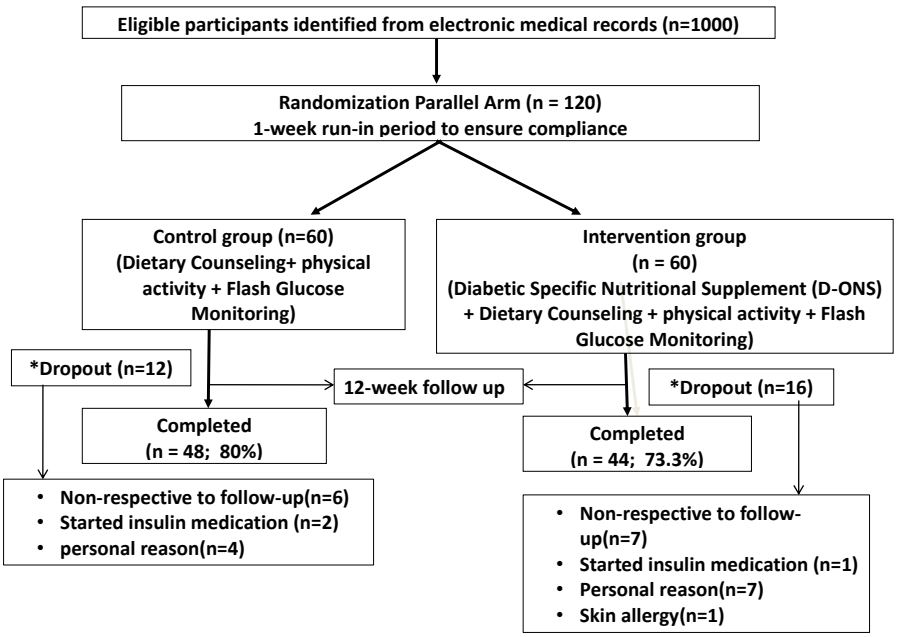


Fig. 1: Study design of the participants

m^2 were advised to consume 2 servings of DSNS supplement mixed with 200mL of water at lunch and dinner time as a part of their prescribed standard (1400 kcal) diet for diabetes. All the eligible participants were given 1-week run-in period to ensure compliance. Participants who completed the run-in period and expressed their willingness to comply and take part in the study were randomized to either intervention or control group. These participants completed the baseline visit, 2 weeks after the run-in period.

The same quantity of DSNS was given to the intervention group based on the BMI as given in the run-in period. Further, participants in the intervention group were instructed not to mix DSNS with hot or cold water and not to consume any supplement other than the allotted quantity of DSNS. Participant compliance was assessed using the dietary 24-hour recall collected by trained dieticians in a face-to-face interview. The average of 3 recalls collected during the 12-week intervention was compared to baseline (3 days dietary recall at baseline). Participants in the intervention arm were also asked to return the empty sachets of DSNS every month. EpiNu nutrient database (Madras Diabetes Research Foundation, India) was used to assess the food and nutrient intake (mainly macronutrients) from the 24-hour dietary recalls.

Outcome Assessments

Anthropometric

Anthropometric measurements including body weight (kg) (electronic OMRON machine; 171 Omron HBF 212, Tokyo, Japan), height (cm), and waist circumference (cm) were measured at baseline, monthly once and at end of study according to standard protocols. Body Mass Index (BMI) was calculated by dividing weight (kg) by height-squared (m^2).

Blood pressure was assessed twice on each occasion (baseline, every month and end of study) at 5-minute intervals using an electronic OMRON machine (Omron HEM 7120, Tokyo, Japan). Participants were seated comfortably with back straight and feet flat on the floor and the average of the two readings was taken.

Biochemical

Fasting (≥8 hours) and postprandial venous blood samples were collected at baseline and visit 2 (30 ± 3 days), visit 3 (60 ± 3 days), visit 6 (90 ± 3 days) into tubes containing EDTA as an anticoagulant. Plasma glucose was estimated using the glucose oxidase-peroxidase method (Roche Diagnostics, Basel, Switzerland). HbA1c was estimated by high-pressure liquid chromatography using the Variant machine (Bio-Rad, Hercules, CA). The Beckman Coulter AU 2700/480 Autoanalyzer (Beckman AU, Olympus, Ireland), was used to measure serum cholesterol (cholesterol esterase oxidase-peroxidase amidopyrine method), serum triglycerides (glycerol phosphate oxidase-peroxidase amidopyrine method), and HDL-C by direct method with poly-ethylene-glycol-pretreated enzymes. LDL-C and VLDL-C were calculated using the Friedewald formula.[10] IFCC UV KINETIC was used to measure SGPT AND SGOT. Renal function tests – urea (GLDH UV Kinetic) and creatinine (JAFFE Kinetic) were also assessed at baseline and end of the study. All the laboratory assessments were done in a National Accreditation Board for Testing and Calibration Laboratories-certified laboratory.

Ambulatory Glucose Profile (AGP) Assessment

A Free Style Libre Pro™ (Abbott Diabetes Care, India) Flash Glucose Monitoring (FGP) System consisting of a reader and a sensor (inserted in the back of the upper arm) was used to analyze the interstitial fluid glucose levels in consenting subjects for AGP assessment. The interstitial fluid glucose levels were assessed at the beginning and at the end of 2 weeks of the study as a measure of participant compliance. The AGP recorded the glucose reading every 15 minutes over a 24-hour period for 14 consecutive days.

Statistical Analysis

Statistical analysis was performed using SAS 9.2 version. Normally distributed data was given as mean ± SD, and as median and IQR for the non-normally distributed data. Baseline demographics and clinical characteristics were estimated using independent t-tests for continuous variables and Pearson chi-square test for categorical variables. Repeated measure ANOVA was used to assess the within group change in anthropometric and blood parameters at different time points. The inter subject differences in health measurements and blood parameters between baseline and 3 months were analyzed using paired sample two-sided t-tests. The differences between intervention *vs.* control group were assessed using the linear models with robust variance estimation under an assumed independence working correlation. Two-sided statistical significance was set at $p<0.05$.

The mean 24-hour interstitial glucose

Table 1: Baseline characteristics of the study participants (Intent-to-treat analysis)

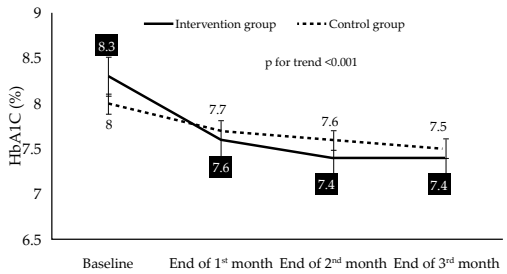
Variables	Control group (n=60)	Intervention group (D-ONS) (n=60)	p value
Age (years)	50.3 ± 8.6	49.6 ± 7.5	0.66
Male n (%)	39 (65%)	36 (60%)	0.35
Height (cm)	162.8 ± 11.1	163.4 ± 8.9	0.73
Weight (kg)	69.6 ± 11.3	70.3 ± 8.7	0.70
BMI (kg/m^2)	26.1 ± 2	26.3 ± 2.1	0.64
WC (cm)	91.3 ± 14.5	91.4 ± 16.5	0.96
SBP (mmHg)	124 ± 13	119 ± 19	0.09
DBP (mmHg)	81 ± 8	77 ± 11.8	0.07
Pulse rate (per minute)	80.1 ± 9.6	79.3 ± 7.7	0.61
Respiratory rate (per minute)	17.6 ±1.8	18.2 ± 2.3	0.29
Diabetes drug (Count/d)	1.5 ± 0.6	1.8 ± 0.6	0.05
Duration of diabetes (years)	7.1 ± 5.7	8.1 ± 5.3	0.33
Fasting plasma glucose (mg/dL)	154 ± 41	148 ± 32	0.40
Post prandial plasma glucose (mg/dL)	252 ± 68	229 ± 57	0.06
HbA1c (%)	8.1 ± 1.0	8.1 ± 0.9	0.68
Serum LDL cholesterol (mg/dL)[a]	100.0 (62.0)	85.0 (42.0)	0.03*
Serum triglyceride (mg/dL)[a]	124.0 (80.0)	129.0 (83.0)	0.76
HDL-cholesterol (mg/dL)[a]	37.0 (10.0)	36.0 (9.0)	1.00
Total cholesterol (mg/dL)[a]	166.0 (74.0)	147 (39.0)	0.06
Hemoglobin (g/dL)	13.5 ± 1.9	13.6 ± 1.5	0.81
Red blood cell count (millicells/cumm)	5.0 ± 0.5	5.0 ± 0.5	0.89
White blood cell count (cells/cumm)	8245 ± 2094	7857 ± 2015	0.31
[$]S.G.O.T (IU/L)	23.2 ± 12.0	25.4 ± 16.4	0.40
[$]S.G.P.T (IU/L)	25.3 ± 14.3	27.6 ± 17.7	0.44
Serum creatinine (mg/dL)	0.7 ± 0.2	0.7 ± 0.2	0.50
Blood urea (mg/dL)	20.6 ± 5.8	21.2 ± 6.3	0.56
Urine protein (g/dL)	17.0 ± 28.8	12.6 ± 13.2	0.31

[$]Significance tested using independent t test; [a]Nonparametric values expressed in median and IQR. Significance tested using Mann-Whitney; Other values are Mean ± SD, All values are Mean ± SD; BMI-Body Mass Index, WC-Waist Circumference, SBP-Systolic blood pressure, DBP-Diastolic blood pressure, FPG-Fasting plasma glucose, PPG-Post prandial glucose, LDL-low density lipoprotein, HDL-High density lipoprotein, SGOT-Serum Glutamic Oxaloacetic Transaminase, SGPT-Serum Glutamic Pyruvic Transaminase, WC-Waist circumference

Table 2: Adjusted mean change in anthropometric and biochemical parameters from baseline in control and intervention

Variables	[$]Adjusted mean change from baseline (End – baseline of study)		p value
	Control group n=48	Intervention group n=44	
Weight (kg)	-0.28 (0.25)	-0.34 (0.26)	0.880
BMI (kg/m^2)	-0.13 (0.09)	-0.14 (0.10)	0.992
WC (cm)	-0.57 (0.35)	-0.76 (0.38)	0.726
SBP (mmHg)	1.37 (1.83)	0.049 (1.95)	0.653
DBP (mmHg)	1.70 (1.25)	1.34 (0.23)	0.455
FPG (mg/dL)	1.5 (5.59)	-18.9 (6.07)	0.020
PPG (mg/dL)	-2.44 (10.32)	-28.74 (11.20)	0.106
HbA1c (%)	-0.48 (0.14)	-0.94 (0.15)	0.039
Total cholesterol (mg/dL)	6.02 (4.6)	-4.94 (5.0)	0.131
Serum triglycerides(mg/dL)	6.91 (8.4)	11.47 (9.1)	0.731
Serum LDL-cholesterol (mg/dL)	3.01 (3.73)	-5.45 (4.05)	0.151
Serum HDL- cholesterol (mg/dL)	0.47	-0.48	0.440
Diabetic medication[ǂ]- Count/d	0.18	-0.22	0.039

*From linear models with robust variance estimation under an assumed independence working correlation; [$]LS Mean - Outcome adjusted for baseline LDL, Diabetic medications (Baseline,1st, 2nd and 3rdmonth), changes in carbohydrate % of Energy (E), protein %E and fat %E; [ǂ]adjusted for baseline LDL and changes in carbohydrate % of Energy (E), protein %E and fat %E; BMI-Body Mass Index, WC-Waist Circumference, SBP-Systolic blood pressure, DBP-Diastolic blood pressure, FPG-Fasting plasma glucose, PPG-Post prandial glucose, LDL-low density lipoprotein, HDL-High density lipoprotein.



*p for trend was tested using one way ANOVA[ǂ]

Fig. 2: Comparison of mean of HbA1c between control (n=48) and intervention (n=44) groups at various time points (adjusted for p<0.001)

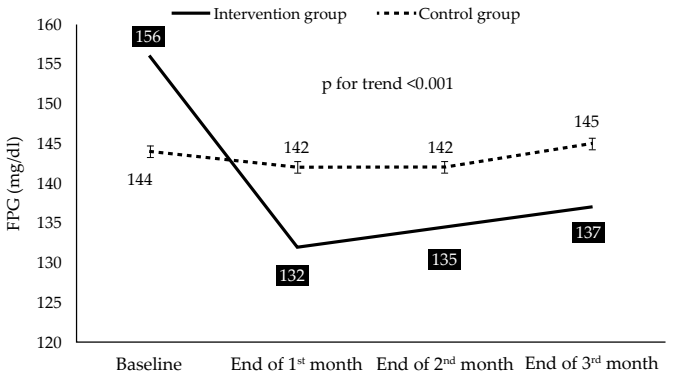
values and incremental Area Under the Curve for glucose (iAUC) over the 14 days at baseline and end of study was calculated for the intervention and control group. Mean Amplitude of Glycemic Excursion (MAGE) was calculated to assess the glycemic variability using a validated algorithm.

Results

A total of 120 participants (60 in each arm), with a comparable gender dispersion, were recruited in the study (Figure 1). Randomization was done using sealed envelopes containing subject group assignment. A total of 48 (80% response rate) in the control arm and 44 (73.3% response rate) in the intervention arm completed the study. Baseline characteristics of the study participants are presented in Table 1. None of the baseline characteristics were significantly different between groups except for LDL cholesterol levels. The mean age of the participants in the control arm was 50.3 ± 8.6 years and 49.6 ± 7.5 years in the intervention arm. None of the participants in the study reported any serious adverse events during the study period. Three participants in the higher BMI group who were recommended to take 2 sachets of DSNS, took only 1 sachet due to diarrhea and hypoglycemia. Empty sachets were collected as mark of compliance from the participants in the intervention group; 91% of the participants who received 1 sachet/day and 96% of the participants who received 2 sachets/day returned the empty sachets.

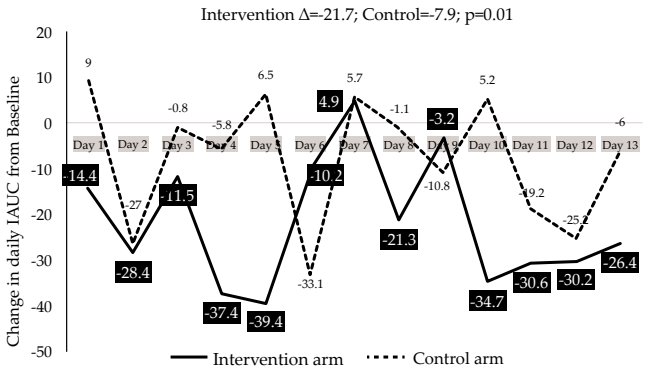
Table 2 describes the overall impact on anthropometric, blood pressure and biochemical parameters at three months in control and intervention groups assessed using linear model. The analysis showed significantly greater change in the intervention group for HbA1c and FPG and a non-significant decrease in PPG values compared to control group. As shown in Figure 2, both the groups showed reduction in HbA1c at three weeks from baseline. A significantly greater decrease was noted in the intervention group compared to control group. As described in Figure 3, there was also a statistically significant impact on FPG values in the intervention group; however, no such change was noted in the control group.

There were no significant inter or intra group differences noted for anthropometric, blood pressure and other biochemical parameters. Within the intervention group, participants who received 2 sachets of DSNS (BMI ≥27.0 - ≤30.0 kg /m^2) showed statistically



*P for trend was tested using one way ANOVA[#]

Fig. 3: Comparison of mean FPG (mg/dL) between control (n=48) and intervention (n=44) groups at various time points (adjusted for p<0.001)



*Fasting values between 6 to 8 am daily was used as base for IAUC calculation

Fig. 4: Change in daily Incremental Area under the Curve (IAUC) from baseline between groups (Intervention and Control) with Flash Glucose Monitoring system

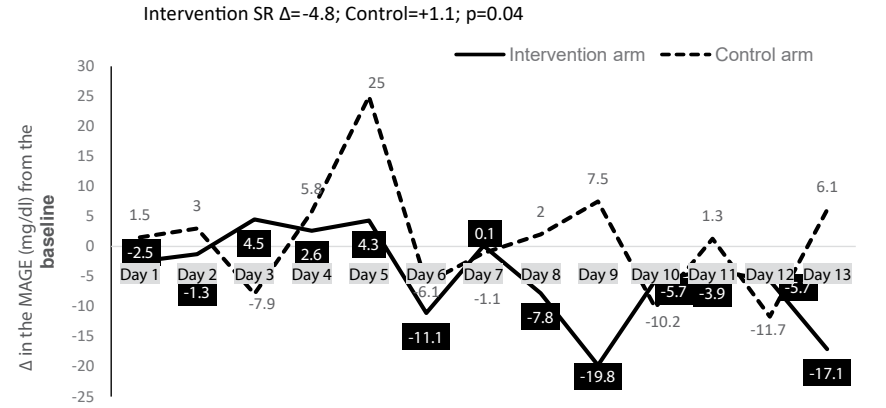


Fig. 5: Change in MAGE from baseline between the intervention and control arm with FGM system

significant reduction in body weight (-0.96 kg, p=0.043) and BMI (-0.36 kg/m^2, p=0.043) compared to those who received 1 sachet post 12 weeks of intervention (BMI ≥23.0 - ≤26.9 kg/m^2).

Though at the beginning, 70 participants agreed to the AGP (intervention, n=42 and control, n=28), due to various personal and practical reasons only 38 participants (intervention, n=25 and control, n=13) completed the AGP studies. The mean 24-hour glucose values of interstitial glucose assessed by AGP significantly decreased in the intervention group from baseline (133.0 mg/dL *vs*. 126.9 mg/dL; p<0.0001), but significantly increased in the control group (149.0 mg/dL *vs*. 157.8 mg/dL; p<0.0001) as shown in Figure 4. There was also a significant reduction (p=0.01) in mean change in iAUC from baseline in the intervention group (Δ -22 mg–15min/dL-average of 13 days of 24-hour glycemic response) compared to the control group (Δ -7.9 mg; between group p=0.01). Figure 5 depicts the change in glycemic variability calculated as MAGE using AGP. There was a significant reduction (from baseline) in the average MAGE value of the intervention group compared to control group (Intervention: -4.8 vs Control: +1.1; p=0.04) corresponding to the iAUC findings. These findings also provide additional evidence for compliance to the consumption of DSNS as partial meal replacement by the intervention group.

There was no significant difference both between and within the control and intervention group for types and number of oral hypoglycemic agents (OHA) consumed per day. While majority of participants in both the groups reported no change in their medications from baseline (control vs intervention: 87.5 vs 72.8%), a greater proportion of subjects in intervention group (13.6%) reported a reduction in OHAs during the course of the study as compared to subjects in the control group (2.1%).

Discussion

The current study evaluated the efficacy of customized dietary counseling with inclusion of DSNS and physical activity to the standard of medical care on glycemic outcomes of T2DM patients over a period of 90 days. Analysis showed that HbA1c was significantly lower after the use of DSNS combined with dietary counseling and physical activity when compared to dietary counseling plus physical activity alone. These results were consistent with previous studies, which used similar diabetes-specific formulas. Chee et al., designed a study to estimate the efficacy of customized dietary counseling with inclusion of DSNS. They randomized 230 overweight/obesity, T2DM patients to either intervention or usual care for 6 months. They showed that HbA1c significantly improved in patients in the intervention group when compared to usual care (-1.1 ± 0.1%, p<0.001).[10]

Many short-term clinical studies demonstrated the advantages of DSNS in extensive diabetes management programs in decreasing HbA1c. Randolph, et al., performed an economic analysis and confirmed that utilization of DSNS is cost effective, as a decrease in HbA1c can help decrease the incidence and severity of diabetes complications, thus decreasing cost of care per quality of life year gained.[11]

In our study, the intervention group showed significant lowering of HbA1C and FPG and a near significant lowering of PPG compared to the standard of medical care. This could be because the subjects in the intervention group received higher fiber through the

DSNS and a part of daily calorie replacement with a low glycemic index supplement. In a 24 week similarly designed study by Sun et al. in China, patients receiving integrated intervention program with inclusion of DSNS showed improved fasting blood glucose ($p<0.05$) and HbA1C ($p<0.001$) compared to standard of medical care. Another study conducted by Mottalib et al., evaluated the effectiveness of two DSNS vs. Oatmeal (OM) in T2DM which showed that PPG was significantly lower after either of the two nutritional supplements when compared to OM.[12] This effect is particularly important in diabetes management since prolonged excursion of PPG is shown to be associated with overproduction of oxygen-free radicals, vasoconstriction and increased circulating levels of pro-inflammatory cytokines that may contribute to cardiovascular complications. Reduced PPG levels lead to a lower need for anti-hyperglycemic medications as well as lower risk of diabetic complications.[13]

The Mean Amplitude of Glucose Excursion (MAGE) was designed to capture mealtime-related glucose excursions. Monnier and Colette proposed a MAGE value of 40 mg/dL as the target level of Glycemic Variability (GV) and found that GV was an independent predictor of chronic diabetic complications in addition to HbA1c.[14] In our study, the GV calculated as MAGE using AGP showed a significant reduction in the intervention group compared to the control group (between group $p=0.04$) which also suggests a good compliance to the consumption of DSNS as partial meal replacement.

Conclusion

It may be concluded from the present study that customized dietary counseling with inclusion of diabetes specific nutritional supplement and physical activity over a period of 90 days is helpful in improving glycemic control in Indian overweight and obese adults with type 2 diabetes, as compared to standard of medical care.

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