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Title : Effect of Simultaneous Vitamin C & B6 Supplementation on Biochemical Values in Type 2 Diabetes Mellitus

Authors : Marya Hossein Mirmiranpour 1, Alireza Esteghamati2*, Maryam Ebadi2, Shahnaz Khaghani3, Siavash Gerayesh- Nejad3, Mohammad Hossein Dehghan1Affiliations:1.Department of Biochemistry, School of Medicine, Alborz University of Medical Sciences, Karaj, Iran 2. Endocrinology and Metabolism Research Center (EMRC), Vali-Asr Hospital, School of Medicine ,Tehran University of Medical Sciences, Tehran, Iran3. Department of Biochemistry, School of Medicine, Tehran University of Medical Sciences, Tehran, IranEmail addresses:Hossein Mirmiranpoor, MD, PHD. Mirmiranpour.h@abzums.ac.irAlireza Esteghamati, MD. Esteghamati@tums.ac.irMaryam Ebadi Ebadi.mary20@gmail.comMohammad Hossein Dehghan. Mohammad.dehghan9@gmail.com *Correspondence to: Alireza Esteghamati, MD, Professor of Endocrinology and Metabolism Endocrinology and Metabolism Research Center (EMRC), Vali-Asr Hospital, Tehran University of Medical Sciences, P.O. Box 13145-784, Tehran, Iran Fax: (+9821)-64432466 Tel: (+9821)-88417918 E-mail: Esteghamati@tums.ac.irRunning Title: Diabetes type 2 & vitamin C & B6 supplementation Abstract word count: 120Text word count: 1925Number of tables: 3Conflict of interest: None declaredm

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Research Paper

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Effect of Simultaneous Vitamin C & B6 Supplementation on Biochemical Values in Type 2 Diabetes Mellitus

Hossein Mirmiranpour [1], Alireza Esteghamati[2*], Maryam Ebadi[2], Shahnaz Khaghani[3], Siavash Gerayesh- Nejad[3], Mohammad Hossein Dehghan[1]

Declaration

The Declaration of the authors for publication of Research Paper in Asian Journal of Modern and Ayurvedic Medical Science (ISSN 2279-0772) Hossein Mirmiranpour [1], Alireza Esteghamati[2*], Maryam Ebadi[2], Shahnaz Khaghani[3], Siavash Gerayesh- Nejad[3], Mohammad Hossein Dehghan[1] the authors of the research paper entitled Effect of Simultaneous Vitamin C & B6 Supplementation on Biochemical Values in Type 2 Diabetes Mellitus declare that , We take the responsibility of the content and material of our paper as We ourself have written it and also have read the manuscript of our paper carefully. Also, We hereby give our consent to publish our paper in ajmams , This research paper is our original work and no part of it or it's similar version is published or has been sent for publication anywhere else.We authorise the Editorial Board of the Journal to modify and edit the manuscript. We also give our consent to the publisher of ajmams to own the copyright of our research paper.

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Abstract

Aims: In this study, we aimed to evaluate the impact of long-term administration of a combination of vitamins B6 and C on the outcome of glycemic control on patients with T2DM.

Methods:A total of 150 patients with T2DM were studied and randomly assigned to 2 groups. Both groups received Metformin and Atorvastatin; the experimental group was supplemented with a combination of vitamin C and B6 for a 6 months trial.

Results: In the experimental group, systolic blood pressure showed a significant decrease.All laboratory measures improved significantly in the experimental group.

Conclusion:A combination of vitamin C & B6 therapy inT2DM can lead to a decline in further complications resulting from increased biochemical values. and may pave the road to a beneficial therapeutic modality.

Keywords: Diabetes Mellitus; Vitamin C; Vitamin B6; Supplementation

Introduction

Type 2 diabetes mellitus (T2DM) is a major metabolic disorder in which apart from hyperglycemia, other detrimental events such as oxidative stress, inflammation and insulin resistance occur, causing damage to vital organs(1). Chronic hyperglycemia is recognized as a mediator of increased reactive oxygen system(ROS) production and decline in antioxidant defense system(2); decreased vitamin level and antioxidant activity are believed to be partly responsible in the increased ROS levels and endothelial dysfunction observed in DM(3).However, the oxidative stress is poorly controlled by oral hypoglycemic agents(1).

Antioxidants imply a promising pharmacologic option in the management of diabetes (2). Previous studies have shown the benefits of administrating antioxidants such as vitamins B6 and C supplementation in DM treatment(4-5). Vitamin C, a scavenger of oxygen free radicals, can reduce blood lipid, glucose(FBG) and hemoglobin A1C (HBA1C) levels and increase insulin sensitivity(5). It has been shown that long term vitamin C supplementation significantly reduces low density lipoprotein (LDL) and oxidant levels and increases blood high density lipoprotein (HDL) concentration. Experimental studies also support the role of vitamin C in regulating triglyceride (TG)levels(6); Moreover, the role of vitamin B6 in reversing some of the metabolic and vascular abnormalities in T2DM has been indicated. It has been proposed that vitamin B6 supplementation reduces blood glucose levels, plasma lipids and HbA1c (4);therefore, vitamin B6 and its derivatives might be useful for diabetic patients and those at risk of developing DM and its complications (7).

Despite current findings regarding the beneficial effects of vitamins B6 and C supplementation separately, a gap exists in understanding the influence of administering a combination of the two. The present study aims to evaluate the impact of administration of a combination of vitamins B6 and C along with Metformin and Atorvastatin on FBG, HbA1c, urine glucose levels, lipid profile and body mass index(BMI)in patients withT2DM.

Materials and Methods

Patients

Between January 2008 and March 2010, medical records of all patients with T2DM (as defined based on the American Diabetes Association) available at the registry of the diabetes clinic of vali-asr hospital (an academic hospital affiliated to Tehran University of Medical Sciences) were reviewed, retrospectively. Patients were considered eligible for the study providing that they fulfilled the following inclusion criteria: 1) diagnosis of T2DM prior to the study, 2) absence of serious co-morbidities 3) lack of end stage complications associated with diabetes including limb amputation, myocardial infarction, cerebrovascular events, diabetic ulcer or significant loss of sight and 4) receiving oral hypoglycemic therapy with no prior insulin injection and finally 5) absence of hypertension or use of antihypertensive medications. Additionally, cases who were lost to follow up at the end of the trial were excluded. Of the 487 cases evaluated, 150 patients (60 males & 90 females) were included in the study. Permuted random block design was used to randomly assign patients into

two groups of 75(30 males & 45 females in each). Experimental and control groups were matched in term of all baseline characteristics and no statistically significant difference was observed among the values (table no. 1)

Assessment

History and physical examination:

A thorough medical history was obtained and physical examination was performed by a single expert physician. Weight was measured using a digital scale (Beurer, GS49, Germany) and recorded with a precision of 0.1 kilogram. Height was measured by a measuring tape and the nearest 0.1 centimeter was recorded. BMI was calculated as weight in kilograms divided by height in square meters(kg/m^2). Using a standard mercury sphygmomanometer (Riester, Big Ben adults, Germany), blood pressure of all cases were measured; after sitting for at least ten minutes, two blood pressure measurements were obtained from the right arm with a five minute interval; the appearance of first Korotkoff sound was regarded as systolic blood pressure (SBP), while diastolic blood pressure (DBP) was defined as disappearance of the fifth sound.

Laboratory evaluations:

Laboratory data including fasting blood glucose (FBG), Glycated hemoglobin A1c(HbA1c), cholesterol(Chol),triglyceride(TG), LDL, HDL concentrations were measured and documented. Blood samples were collected following 12 hours of fasting. Briefly, ten milliliters of brachial venous blood was drawn; after centrifugation at 2000g and 4°c for 15 min, plasma was collected and stored at -80°C until assay. FPG was measured within 24 hours of blood collection using the Glucose Oxidase Method(GOD)(8). By applying a high performance liquid chromatography(HPLC) method HbA1c levels were measured(9). Samples for determining the lipid profile including total Chol, high-density lipoprotein cholesterol(HDL-c), low-density lipoprotein cholesterol (LDL-C), and TG were stored and analyzed within 2 weeks using enzymatic methods with commercially available kits (Pars Azmun, Karaj, Iran).

Trial

Written consents were obtained from all participants after providing them with adequate information. The study protocol was approved by Tehran University of Medical Sciences board of ethics and was in accordance with the guidelines laid down in Helsinki declaration (October 2008).

In a six months trial, the experimental group received Atorvastatin tablet (20 mg, daily) Metformin tablet(500 mg, twice daily), oral vitamin C tablet (500mg, twice day) and vitamin B6 tablet(40mg, twice day); subjects of the control group received similar doses of Atorvastatin and Metformin along with placebos. Clinical and biochemical evaluations were performed prior to and after the trial and results were compared.

Statistical analysis

Statistical analysis was performed using Statistical Package of Social Science software (SPSS Inc., Chicago, USA) version 16. All data are expressed as mean± standard deviation(SD). Statistical analysis was tested by one way analysis of variance(ANOVA). Values were compared using chi-square test. A P value ≤0.05 was considered statistically significant. Multiple comparisons of clinical and laboratory variables of the two groups before and after the trial were performed.

Results

Among the experimental group, SBP showed a significant decrease after the trial from 134.42±1.23 to 122.46±1.7 (p=0.00); other clinical characteristics (weight, BMI and DBP) failed to show a significant difference. SBP decreased in 35(46.66%) patients, remained intact in 25(33.33%) and increased in the other 15(20.1%), while DBP and weight declined in 28(37.33%) and 433(57.33%) patients, with no statistically significant difference. Means of all clinical data before and after the trial are presented in table no. 2. All laboratory values (FBG, HbA1c, Chol, TG, LDL and HDL) differed significantly(table no. 3); FBG changes were mostly correlated to vitamin therapy, as values decreased in 56(74.6%), stabilized in 4(5.3%) and increased in 15(20.1%). Other values, HbA1c, Chol, TG, HDL and LDL, improved in 42(56%), 42(56%), 47(62.66%), 43(57.33%) and 41(54.66%) patients, respectively. In the control group, no significant improvement in clinical characteristics was observed after the trial (table no.2); decline in systolic and diastolic blood pressure was observed only in 2(2.66%) patients. All laboratory values failed to show a significant improvement after the trial.(table no.3)

Discussion

In this study, we aimed to investigate the therapeutic effect of supplementation with a combination of vitamin C & B6 on T2DM. A total of 150 patients (60 males & 90 females) who fulfilled the inclusion requirements were included and randomly assigned to two groups of patients and control. Prior to the study, clinical and laboratory variables were measured. All individuals received Atorvastatin (20 mg, daily) and Metformin Tablet(500 mg, twice daily), while the experimental group was supplemented with oral vitamin C tablet (500mg, twice day) and vitamin B6 (40mg, twice day). After the six months trial, both groups were assessed for laboratory values and clinical characteristics; values were compared between the two groups and each group with its baseline measures.

Previous studies have proven that antioxidant vitamins have a positive role in DM treatment (4-5). The inverse correlation between vitamin C and FBG levels in DM patients has been reported in multiple studies (5, 10-13), however, Chen et al, found no significant improvement in insulin resistance and endothelial dysfunction in T2DM patients after high-dose oral vitamin C therapy (14). Child et al, reported that HbA1c and vitamin B6 levels in plasma are conversely correlated; moreover, they suggested a vital role for vitamin B6 in decreasing plasma Chol and TG levels and increasing HDL(15). A similar relation between FBG and vitamin B6 levels were found in other studies (4, 16-17). El-Azal et al, reported that vitamin E & C supplementation combined with statins is associated with a promising outcome in terms of management of T2DM(18). Dakhale et al, investigated the effect of vitamin C supplementation along with Metformin in a double-blind, placebo-controlled , 12-week study and concluded that among the experimental group FBG, post-meal blood glucose(PMBG) and HbA1c improved significantly(19). The mechanism through which vitamins exert their therapeutic effects have been studied. In T2DM, supplementation of vitamins encourages the antioxidant activities (20). It is proven that protein glycation in diabetes leads to the formation of advanced glycation end products (AGEs) and free radicals released form AGEs damage cells and cause diabetic complications. Ahmed et al, reported that vitamin B6 supplementation is effective in suppressing AGEs

levels(21); this vitamin inhibits protein glycation and maintains the renal parameters at normal levels (22). By protecting the renal cells against several kinds of damages, vitamin B6 plays a positive role in the treatment of diabetic nephropathy (23).

To the best of our knowledge, this is the first study to report the effects of simultaneous vitamin C & B6 supplementation combined with Metformin and Atorvastatin on non-insulin dependent diabetes mellitus (NIDDM) patients ; the outcome of vitamin B6 and C supplementation on T2DM has been studied individually, here we combined the two in order to investigate possible synergistic effects. No significant improvement was observed in the control group, whereas, changes in all laboratory variables and the systolic blood pressure were statistically significant among the experimental group after the six months trial; FBG and HbA1c levels decreased in 74.6% and 56% of patients, respectively; FBG level was mostly affected by the combination vitamin therapy, while DBP showed the least correlation, with only decrease in 37.33% after the six months trial. Changes in all parameters in the experimental group were significant compared to the control group. No significant change was observed in the same variables among the control group. Means of HbA1c and FBG levels and weight decreased significantly($p<0.05$)in the experimental group, conferring to improvements in metabolic events besides reflecting the benefits of vitamins B6 and C supplementation. The course of changes in the control group wasn't favorable after the mentioned period of time and there was a weak outlook. Although a statistically meaningful correlation between weight and FBG after the treatment wasn't found, the comparison between the P-values indicated that the correlation became stronger. There were positive meaningful correlations between weight and HbA1c and between FBS and HbA1c levels after treatment, indicating the dependence of severity and process of disease from biochemical changes. A decrease in weight due to improvement in HbA1c and an association between FBS and HbA1c reduction were indicated.

It has been demonstrated that vitamin B6 supplementation for a two month period, neutralizes oxidants and normalizes plasma lipids and HbA1c (4).Despite the proven benefits of antioxidant vitamins on T2DM , supplementation with folic, vitamin B6 and B12 hasn't been found to attenuate progression to T2DM in high-risk patient population(24), conferring that it may have a proven therapeutic role, but no proven preventive effect.

The limitations of this study bear mention; as our study wasn't double-blinded, results might have been biased; moreover, assessment and comparison of further development of major complications between the two recent groups could have strengthened the value of our findings.
Conclusion

This study demonstrates the useful effects of combined vitamin C and B6 supplementation along with Metformin and Atorvastatin therapy on improvement of laboratory values in NIDDM patients and propose it as possible therapeutic modality. Further double-blinded, placebo controlled studies are recommended to support our hypothesis.

Abbreviations:

T2DM: type 2 diabetes mellitus **; AGEs:** advanced glycation end products;
NIDDM: non-insulin dependent diabetes mellitus; **PMBG:** post-meal blood glucose; **FBG:** fasting blood glucose; **HbA1c:** Glycated hemoglobin A1; **Chol:** cholesterol; **TG:** triglyceride

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Table no.1. Comparison of baseline characteristics between patients and control groups

Parameters	Patients	Controls	P value
Age(yrs)	58.85 ± 1.11	58.85 ± 1.11	0.99
Weight(kg)	77.25 ± 1.52	75.89 ± 1.59	0.83
BMI(Kg/m^2)	27.42 ± 0.35	26.95 ± 0.72	0.83
Systolic blood pressure(mmHg)	134.42 ± 1.23	132.01 ± 0.99	0.20
Diastolic blood pressure(mmHg)	68.93 ± 0.66	65.77 ± 0.64	0.56
FBS (mg/dl)	204.89 ± 3.53	202.09 ± 5.06	0.96
HbA$_1$C	7.74 ± 0.09	7.71 ± 0.08	0.99
Cholesterol(mg/dl)	181.29 ± 2.57	179.72 ± 2.92	0.98
TG (mg/dl)	176.80 ± 1.04	176.08 ± 1.23	0.99
HDL (mg/dl)	81.42 ± 1.13	81.80 ± 1.74	0.99
LDL (mg/dl)	131.96 ± 1.41	131.33 ± 1.18	0.99

Data are expressed as mean ± SD, Differences are considered significant if p<0.05.

Table no. 2. Demographic characteristics before and after the trial

	Before treatment	After treatment	P value
Treatment group			
Age(yrs)	**58.85 ± 1.11**	**58.85 ± 1.11**	**1.00**
Weight(kg)	**77.25 ± 1.52**	**76.70 ± 1.76**	**0.98**
BMI(Kg/m^2)	**27.42 ± 0.35**	**27.14 ± 0.43**	**0.97**
Systolic blood pressure(mmHg)	**134.42 ± 1.23**	**122.46 ± 1.70**	**0.00**
Diastolic blood pressure(mmHg)	**68.93 ± 0.66**	**66.72 ± 0.98**	**0.31**
Control group			
Age(yrs)	**58.85 ± 1.11**	**58.85 ± 1.11**	**1.00**
Weight(kg)	**75.89 ± 1.59**	**75.75 ± 1.05**	**0.97**
BMI(Kg/m^2)	**26.95 ± 0.72**	**26.88 ± 0.08**	**0.98**
Systolic blood pressure(mmHg)	**132.01 ± 0.99**	**121.96 ± 1.07**	**0.92**
Diastolic blood pressure(mmHg)	**65.77 ± 0.64**	**65.69 ± 0.67**	**0.91**

Data are expressed as mean ± SD, Differences are considered significant if p<0.05.

Table no. 3 Biochemical characteristics before and after the trial

	Before treatment	After treatment	P value
Treatment group			
FBG (mg/dl)	**204.89 ± 3.53**	**183.78 ± 4.63**	**0.00**
HbA_1C	**7.74 ± 0.09**	**7.32 ± 0.07**	**0.02**
Cholesterol(mg/dl)	**181.29 ± 2.57**	**166.09 ± 3.25**	**0.00**
TG (mg/dl)	**176.80 ± 1.04**	**138.17 ± 1.36**	**0.00**
HDL (mg/dl)	**81.42 ± 1.13**	**86.78 ± 1.42**	**0.00**
LDL (mg/dl)	**131.96 ± 1.41**	**120.01 ± 1.28**	**0.00**
Control group			
FBG (mg/dl)	**202.09 ± 5.06**	**195.50 ± 3.67**	**0.99**
HbA_1C	**7.71 ± 0.08**	**7.66 ± 0.09**	**0.99**
Cholesterol(mg/dl)	**179.72 ± 2.92**	**176.61 ± 2.69**	**0.91**
TG (mg/dl)	**176.08 ± 1.23**	**168.78 ± 1.21**	**0.36**
HDL (mg/dl)	**81.80 ± 1.74**	**82.24 ± 1.49**	**0.99**
LDL (mg/dl)	**131.33 ± 1.18**	**128.80 ± 1.25**	**0.69**

Data are expressed as mean ± SD, Differences are considered significant if $p<0.05$.