IN THE NAME OF GOD

Effect of Vitamin B6 Supplementation on Biochemical Values in Type2 Diabetes Mellitus

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INTRODUCTION

Diabetes mellitus

- **Diabetes mellitus (DM) is a common metabolic disorder that follows from insulin deficiency or defect in response of body to insulin and characterized by hyperglycemia.**

- **There are two types of DM: 1(I) and 2(II).**

- **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.**

- **Chronic hyperglycemia is recognized as a mediator of increased reactive oxygen system (ROS) production and declines in antioxidant defense system.**

Antioxidant

- **Decreased vitamin level and decreased antioxidant activity are believed to be partly responsible in the increased ROS levels in DM.**

- **Antioxidants imply a promising pharmacologic option in the management of DM.**

- **The benefit of administrating antioxidants such as vitamin supplementation in DM treatment has been known.**

Vitamin B6

- **The role of vitamin B6 in reversing some of the metabolic and vascular abnormalities in T2DM and treatment of this disease has been indicated.**

- **A group of studies has proposed that vitamin B6 supplementation reduces blood glucose levels, plasma lipids and HbA1c.**

- **Vitamin B6 and its derivatives might be useful for diabetic patients and those at risk of developing DM and its complications.**

Objective

- **The present study aims to evaluate the impact of administration of a combination of vitamin B6 along with Metformin and Atorvastatin on FBG, HbA1c, advanced oxidation protein products (AOPP), advanced glycation end products (AGEs), lipid profile and anthropometric parameters in patients withT2DM.**

Materials and Methods

Patients

- **Patients with T2DM were recruited through diabetes clinic of Vali-Asr hospital (an academic hospital affiliated to Tehran University of Medical Sciences) from January 2010 to March 2012.**

- **Medical records of all patients (as defined based on the American Diabetes Association) were assessed.**

- **150 patients (60 males & 90 females) were included in the study.**

- **Patients were divided into two groups [experimental (75) and control (75)]. 30 males & 45 females contributed in each group.**

Trial

- **In a six months trial, the experimental group received atorvastatin tablet (20 mg, daily) metformin tablet (500 mg, twice daily), oral vitamin B6 tablet (40mg, twice daily).**

- **Subjects of the control group received similar doses of atorvastatin and metformin along with placebo.**

- **Clinical and biochemical evaluations were performed prior to and after the trial and results were compared.**

Anthropometric parameters

- **Patients were interviewed according to a pre-designed questionnaire and underwent a thorough physical examination.**

- **Anthropometric parameters including age, weight, BMI, height and blood pressure of all patients were analyzed.**

- **All of recent parameters were measured by related methods.**

Laboratory parameters

- **Laboratory data including fasting blood glucose (FBG), Glycated hemoglobin A1c(HbA1c), cholesterol, triglyceride, LDL, HDL, AGEs and AOPP concentrations were measured and documented.**

- **Blood samples were collected following 12 hours of fasting.**

- **AGEs and AOPP by spectrophotometric method, FBG and lipid profile by enzymatic method and HbA1c by HPLC method were measured.**

Statistical analysis

- **Statistical analysis was performed using Statistical Package of Social Science software (SPSS Inc., Chicago, USA) version 16.**

Results

Anthropometric parameters

- **After the trial, among the experimental group, systolic blood pressure showed a significant decrease after the trial from 134.42±1.23 to 122.46±1.7 (p=0.00)**

- **Weight, BMI and diastolic Blood Pressure failed to show a significant difference.**

- **However, diastolic Blood Pressure and weight declined in 28(37.33%) and 43 (57.33%) patients, respectively, with no statistically significant difference.**

Laboratory parameters

- **All laboratory values including FBG, HbA1c, AGEs, AOPP, cholesterol, triglyceride, low density lipoprotein (LDL) and high density lipoprotein (HDL) were differed significantly in experimental group.**

- **FBG changes were mostly correlated to vitamin therapy, as values decreased in 56 (74.6%) patients.**

- **The improvement of other laboratory changes including: HbA1c 42(56%), Cholesterol 42(56%), triglyceride 47(62.66%), HDL 43(57.33%), LDL 41(54.66%), AOPP 42(56%) and AGEs 41(54.66%) in experimental group were shown.**

Control group

- **In the control group, no significant improvement in anthropometric parameters was observed after the trial.**

- **All laboratory parameters failed to show a significant improvement after the trial.**

Anthropometric parameters of patients before and after 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 $p<0.05$.

Laboratory parameters of patients before and after 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 $p<0.05$.

Oxidant parameters of experimental group before and after trial

Laboratory parameters	Before treatment	After treatment	P value
AGEs (%)	67.24 ± 3.99	62.34 ± 8.51	0.04
AOPP (µmol/l)	136.51 ± 26.58	119.43 ± 35.44	0.01

Oxidant parameters of control group before and after trial

Laboratory parameters	Before treatment	After treatment	P value
AGEs (%)	68.12 ± 4.53	66.29 ± 3.47	0.98
AOPP (µmol/l)	133.51 ± 26.58	129.51 ± 27.62	0.97

Conclusion

- **This study demonstrates the useful effects of combined vitamin B6 supplementation along with Metformin and Atorvastatin therapy on improvement of laboratory and oxidant values in NIDDM patients.**

Thank You