Journal of Clinical & Translational Endocrinology 10 (2017) 28–35

Contents lists available at ScienceDirect

Journal of Clinical & Translational Endocrinology

journal homepage: www.elsevier.com/locate/jcte

Original research

Effect of a vitamin and mineral supplementation on glycemic status: Results from a community-based program

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ARTICLE INFO

Keywords:
Prediabetes
Type 2 diabetes mellitus
Vitamin D
Nutritional supplements
Multivitamin
Normoglycemia

ABSTRACT

Aims: Diet is a major risk factor for type 2 diabetes mellitus. As cofactors necessary for enzyme function of all metabolic pathways, vitamins and minerals have the potential to improve glucose metabolism. We investigated the effects of a nutrient intervention program on glycemic status.

Methods: We used a form of natural experiment to compare Pure North program participants (n = 1018) that received vitamin D alone (Vital 1) or vitamin D in combination with other nutrients (Vital 2) during two different time periods. Changes in 25-hydroxyvitamin D [25(OH)D], high-sensitivity C reactive protein (hs-CRP), glycated hemoglobin (HbA1c) and glycemic status were characterized over one and two years.

Results: Serum 25(OH)D concentrations increased significantly in both Vital 1 (to 111 ± 49 nmol/L) and Vital 2 (to 119 ± 52 nmol/L) over one year. HbA1c and hs-CRP were significantly reduced over time in Vital 2. Higher 25(OH)D levels after one year were associated with larger decreases in HbA1c and hs-CRP in Vital 2. At one year, 8% of Vital 2 and 16% of Vital 1 participants progressed from normoglycemia to prediabetes/diabetes, whereas 44% of Vital 2 and 8% of Vital prediabetes/diabetes subjects regressed to normoglycemia.

Conclusions: Vitamin D combined with other nutrients was associated with a reduced risk of progression to diabetes and with an increased rate of reversion to normoglycemia in high risk participants. The results suggest that nutrient supplementation regimes may provide a safe, economical and effective means for lowering diabetes risk. Further examination of this potential via randomized controlled trials is warranted.

Introduction

World-wide, 347 million people have diabetes mellitus, with type 2 diabetes constituting 90% of cases [1,2]. Diabetes is one of the most common chronic diseases in Canada, with a 70% increase in prevalence between 1999 and 2009 [3]. The prevalence of type 2 diabetes is highest in older persons, but over 50% of the affected population are of working age [3]. The economic burden associated with direct and indirect medical costs is estimated at $12.2 billion annually [4]. There are known modifiable lifestyle risk factors for type 2 diabetes that provide the opportunity for intervention and prevention [5]. The possibility of modifying the risk of diabetes by improving nutrient levels may offer a simple, safe and scalable strategy to reduce the burden of this prevalent chronic disease.

While lifestyle interventions tend to be the primary focus of diabetes prevention strategies, other strategies are also used, such as bariatric surgery or the use of pharmacological agents [6]. High intensity programs, such as the US Diabetes Prevention Program, have demonstrated up to a 58% reduction in relative risk of diabetes [7]. However, such studies often have protocols that are labour intensive, expensive and severely limited in their capacity to be implemented in a community setting [8].

The development of an inexpensive and more easily implemented intervention program for the prevention of diabetes could play a role in improving the health of individuals worldwide. The use of nutritional supplements as part of such an intervention strategy is an area that merits investigation. The development of diabetes is preceded by abnormalities in glucose homeostasis leading to insulin resistance, glucose intolerance and eventually the development of type 2 diabetes [9]. It has been postulated that daily variation in glucose homeostasis may be aggravated by inadequate nutrient composition as many micronutrients are necessary cofactors for the proper function of enzymes involved in energy metabolism. The role of dietary supplements in glucose control has been investigated in basic research and observational studies as a

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https://doi.org/10.1016/j.jcte.2017.11.002
Received 6 July 2017; Received in revised form 31 October 2017; Accepted 6 November 2017
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means to address inadequate nutrition and chronic disease [10,11]. Nutrients with proposed benefit in glucose homeostasis include vitamin D, vitamin K, calcium, magnesium, zinc, chromium, and omega-3 fatty acids [12,13]. Vitamin D, in particular, appears to play a significant role in the progression of diabetes, with studies linking low serum 25(OH)D levels with both insulin resistance and β-cell dysfunction [14,15]. However, randomized clinical trial evidence for individual nutrients, including vitamin D, is inconsistent; some trials show benefit while others report null results which may only reflect the differences in study design [16,17]. It is also possible that a combination of nutrients is required to derive benefit. In this study we characterize the effect of a nutritional intervention program, utilizing a natural experiment in which two supplement groups occur, on glycemic status over one and two years.

Patients and materials and methods

Study design

This study is a form of a "natural experiment" [18] where two groups were retrospectively identified, Vital 1 (Dec. 2008 to Mar 2010) and Vital 2 (Mar. 2010 to May 2012). We compare the effect of the different interventions received by the two groups on glycemic status and development of type 2 diabetes mellitus.

This was a retrospective database analysis. This study focused on participants who joined the program between December 2008 and May 2012 and was approved by the research ethics board at the University of Calgary (E-24890). Participants provided written informed consent for the use of their data for research.

The Pure North community-based program (intervention)

Pure North S'Energy Foundation is a not-for-profit wellness program based in Calgary, Alberta, Canada, that focuses on the prevention of chronic disease. The Pure North program offers lifestyle advice, education and nutritional supplements to participants. There is no inclusion/exclusion criteria for entering the program and the program does not substitute for conventional health care. The nutritional supplements provided by the Pure North program are selected to address common problems such as vitamin D deficiency.

The core tenant of the program is to achieve optimal nutritional status with a focus on physiological levels of vitamin D. All participants are encouraged to achieve a 25(OH)D level above 100 nmol/L (< 250 nmol/L); levels that can be naturally attained through regular sun exposure [19], are safe [20,21], and associated with a reduced risk of many chronic diseases including bone disease [22,23], depression [24], autoimmune disease and cancers [25,26].

Because of large inter-individual response differences to a given dose of vitamin D3, dosages were adjusted accordingly for the individual to achieve the target serum 25(OH)D level by the treating health care professional. Vitamin D3 doses were often above the upper level of intake, 4000 IU/d, to achieve the target. Vitamin D3 intake recommendations ranged from 1000 to 20,000 IU/d [26] under medical supervision.

In the program, each participant meets with a health care professional (Medical Doctor, Naturopathic Doctor or Nurse Practitioner) who provides lifestyle advice appropriate for the individual participants' health goals and current diagnoses. Dietary advice is provided as deemed appropriate, such as the DASH diet for patients with cardiovascular disease or risk factors like hypertension or hyperlipidemia. There is generally a focus on increasing vegetable and fruit intake and reducing processed foods as only 50% of the Canadian population is consuming more 5 servings of vegetables and fruit daily and the recommendation is for 7–10 servings daily. Exercise that is appropriate for the participants' health is recommended to ensure cardiovascular health and muscle strength. This applied to both the Vital 1 and Vital 2 groups.

Intervention groups

We exploit changes in the program to compare two groups that differed in their supplement intake: Vital 1 and Vital 2. The group construction was based on dates when the program difference occurred. Supplement composition was the only major difference in the program experienced by Vital 1 and Vital 2; other aspects of the program remained consistent between the two groups.

Vital 1

The Vital 1 multivitamin supplement (Table S1) was introduced to the program in December 2008 and was given in combination with a liquid vitamin D_3 supplement (1000 IU/drop; Ddrops®, Toronto, ON). Vital 1 contained 200 mg of niacin, twice daily, for a total of 400 mg/d of niacin. An informal survey of participants in the Vital 1 cohort suggested a very low compliance with the multivitamin as a result of the flushing produced by the niacin. The lack of change in serum vitamin B12 levels despite an increase in serum 25-hydroxyvitamin D [25(OH)D] levels was consistent with the low level of compliance with Vital 1 (Fig. 1), but supported compliance with vitamin D_3 supplements. Thus, the Vital 1 cohort is referred to as the "Vitamin D_3 only group."

Vital 2

Over time the Vital 1 multivitamin was reformulated, niacin was reduced to 15 mg, and the new multivitamin was named Vital 2. The Vital 2 formulation (Table S1) was introduced in March 2010. At the same time other supplements were incorporated creating the "full program." The core supplements of the full program were vitamin D_3 (1000–20,000 IU/d as needed to achieve target levels), Vital 2 (multivitamin), and omega-3 fatty acids (400 mg EPA and 200 mg DHA). Additional supplements were recommended on a discretionary basis, in response to deficiency or clinical indication, including vitamin C, magnesium, caprylic acid, PGX (PolyGlycopleX®) and probiotics. These were reported by participants and used for covariates in statistical models where appropriate.

When building the dataset, not all of the participants included in the Vital 1 and Vital 2 groups at one year are included at two years (lost to follow-up). As such, this results in slightly different baseline values and we have presented baseline versus one year and baseline versus two years for each Vital cohort separately to allow a direct comparison

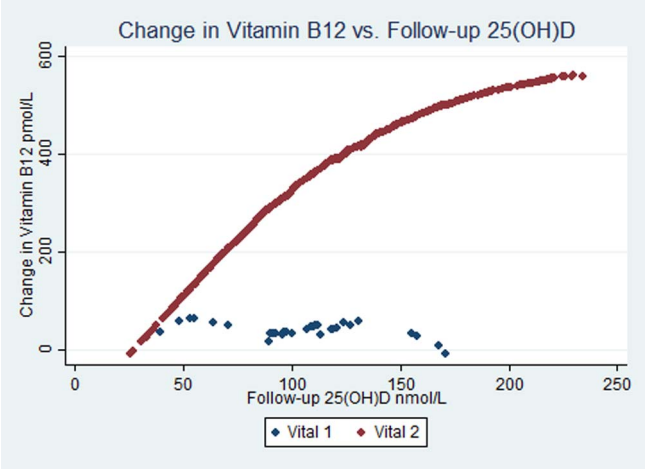

Fig. 1. Establishing Groups Vital 1 versus Vital 2. Comparison of Vitamin B12 and 25(OH)D changes at one year in each multivitamin cohort. In Vital 1 participants only vitamin D increases over one year suggesting that they are not taking the multivitamin containing vitamin B12. The proportional increase in vitamin D and B12 in Vital 2 suggests that Vital 2 participants are consuming both vitamin D and the multivitamin (containing vitamin B12) and supports the assumption of two groups.

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