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Original article

Efficacy and tolerance of a diabetes specific formula in patients with type 2 diabetes mellitus: An open label, randomized, crossover study

Seema Gulati [a,b,c], Anoop Misra [a,b,c,d,e,*], Kriti Nanda [b,c], Ravindra M. Pandey [f], Vivek Garg [g], Sanjeev Ganguly [g], Lorena Cheung [h]

[a] Diabetes Foundation (India), SDA, New Delhi, India
[b] National Diabetes, Obesity and Cholesterol Foundation (N-DOC), SDA, New Delhi, India
[c] Center of Nutrition & Metabolic Research (C-NET), SDA, New Delhi, India
[d] Fortis C-DOC Center for Excellence for Diabetes, Metabolic Disease and Endocrinology, New Delhi, India
[e] Fortis Flt. Lt. Rajan Dhall Hospital, Vasant Kunj, New Delhi, India
[f] All India Institute of Medical Sciences (AIIMS), New Delhi, India
[g] Nestlé India Limited, Gurgaon, India
[h] Nestlé Health Science, AOA region, Singapore

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ABSTRACT

Aim: This study evaluated the effect of a diabetes specific formula on acute glucose, insulin, and triglyceride responses in patients with type 2 diabetes mellitus (T2DM).
Methods: This open-label, randomized, crossover, pilot single center study had two phases (pre-treatment and treatment). After screening, the patients entered run-in period and were counseled on diet and exercise regime. They were then randomly allocated to receive either diabetes specific formula (Nutren® Diabetes, Nestlé Health Science, Switzerland; Group A) or isocaloric meal (Cornflakes and milk; Group B). Blood samples were collected to estimate blood glucose, insulin and triglyceride levels (Baseline at 0 min and post-meal at 30, 60, 120, and 180 min).
Results: Area under curve for blood glucose post-meal at 30 min, 60 min, 120 min, and 180 min was significantly lower for Group A as compared with Group B ($p = 0.003$, 0.0001, 0.0001, 0.0001, respectively). Increase in serum insulin levels from baseline was also lower for Group A post-meal at 120 and 180 min, respectively, as compared to Group B ($p = 0.0001$ and 0.0002, respectively).
Conclusion: The Diabetes specific formula tested in this study showed lower post-meal blood glucose and insulin levels as compared with isocaloric meal. Thus, diabetes specific formula may be an option for diabetic and hyperglycemic patients in need of nutritional support.

Introduction

Diabetes mellitus is a global public health problem and has considerable morbidity and mortality [1]. About 382 million people were reported to have diabetes in 2013 and this number is expected to increase to 592 million by the year 2035 [2]. In the year 2012 alone, 4.8 million deaths related to diabetes were reported worldwide [1]. The prevalence of diabetes is rising across the world with Asia emerging as a region of exponential growth in the proportion of people with diabetes. More than 80% of the world's population with diabetes comes from Asia [2–4].

South-East Asia has the second largest pool of diabetes, there are 100 million people having diabetes in China and 65 million in India [2]. India often referred to as the "diabetic capital of world" has the second largest number of people with type 2 diabetes mellitus (T2DM) in the world [2]. Common contributing factors are; irregular meals, frequent snacking of foods rich in simple carbohydrates, sugars, fats and trans fats; consumption of diet poor in fruits/vegetables and work stress; leading to weight gain, hyperglycemia, poor glycemic control and risk of cardiovascular disease (CVD) [5,6].

The first phase of community-based survey of 218 million individuals (from 4 states representing north, south, east, and west India) conducted by the Indian Council of Medical Research–India Diabetes (ICMR–INDIAB) revealed that there were 62.4 million

* Corresponding author at: Fortis-C-DOC Center of Excellence for Diabetes, Metabolic Diseases and Endocrinology, B-16, Chirag Enclave, New Delhi 110048, India. Tel.: +91 11 4277 6222x5030; fax: +91 11 4277 6221.
E-mail address: anoopmisra@metabolicresearchindia.com (A. Misra).

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people with T2DM and 77.2 million people with pre-diabetes in 2011 [7].

Post-meal hyperglycemia that occurs frequently in people with T2DM is associated with cardiovascular risk and related outcomes [7]. Due to factors like genetic makeup, high familial aggregation, obesity (especially central), insulin resistance and lifestyle changes due to rapid urbanization, Asian Indians are more prone to develop post prandial hyperglycemia [6]. Misra et al. in their review on obesity and metabolic syndrome in developing countries concluded that a focus on increased physical activity and healthier food options is an urgent need to prevent increasing morbidity and mortality due to obesity-related T2DM and cardiovascular disease [8]. Both non-pharmacologic and pharmacologic therapies are needed to target post-meal plasma glucose levels and diabetes management. Medical Nutrition Therapy (MNT) is the cornerstone of diabetes management along with physical activity and anti-diabetic drug therapy [9–12]. The International Diabetes Federation (IDF) post-meal glucose 2011 guidelines suggest that diets with a low glycemic load are beneficial in improving the glycemic control (Level 1+) [7]. Over the past several years, different enteral formulations for oral nutritional supplement or tube feed have been specifically developed for the patients with diabetes. Standard enteral diabetes-specific formulae are generally high in carbohydrate (mostly low–molecular weight sources), low in fat, and high in fiber [13]. For this reason, diabetes-specific formulae that contain a modified nutrient composition designed to enable a better glycemic control have been developed [14].

There is an immediate need of dietary substitutes in India to manage the growing menace of T2DM. Moreover, there is a paucity of data about diabetes related dietary substitutes in India. The present study was conducted to evaluate the efficacy and safety of a diabetes specific formula in maintenance of glycemic parameters in patients with T2DM. The study was registered at www.ctri.nic.in with Reg. No. CTRI/2011/10/002089.

Subjects

Patients (35–60 yr) with a known history of T2DM having baseline HbA1c levels of 7.0–9.0%, fasting blood glucose <180 mg/dl, with stable body weight within the past 6 months (not more than 10% change) and currently on anti-diabetic drugs, were eligible to participate in the present study. Those on insulin therapy; serum creatinine levels >1.3 mg/dl (female) or 1.4 mg/dl (male), evidence of hepatic disease or a history of chronic alcohol abuse; history of hypersensitivity to any of the ingredients of diabetes specific formula; history of hypersensitivity to any of the ingredients of test meal; pregnant and lactating females were excluded from the study.

Materials and methods

Study design

This was an open labeled, randomized, single center, and crossover pilot study to evaluate the efficacy of Nutren® Diabetes (Nestlé Health Science, Switzerland)—a diabetes specific formula, in maintenance of postprandial blood glucose level in patients with T2DM. This study was conducted at the Fortis Center of Excellence for Diabetes, Obesity and Cholesterol, New Delhi, India from August 2011 to April 2012. The study had two phases (Pre-Treatment and Treatment) and three patient visits. Following the screening period (Day −14 to Day −7), eligible patients entered the run-in period (Day −7 to Day −1), where they were counseled on diet and exercise regime. At the end of run-in period, the patients were randomly allocated to receive either the diabetes specific formula (Group A) or an isocaloric meal (Cornflakes and milk, Group B) (Fig. 1). This diabetes specific formula is composed of a protein blend of potassium caseinate (50%) and whey protein (50%), a fiber blend of acacia gum (24%), outer pea fiber (34%) and inulin (12.5%), a fat blend of high oleic sunflower oil (69%), rapeseed oil (24%), low erucic soy lecithin (5%), milk fat (2%), and a carbohydrate blend of tapioca starch and potato starch as its main ingredients. It is a complete and nutritionally balanced formula which may be used as tube feed or oral nutrition supplement, for short or long-term feeding.

The quantity of diabetes specific formula administrated to participants was 55 g in 210 ml of water to make 250 ml at standard reconstitution (1 kcal/ml). The quantity of isocaloric meal was 42 g of cornflakes in 250 ml of milk. The products were administrated to participants after overnight fasting of 8 to 10 h. The participants were instructed to consume the meal within a 15-min period and were allowed to have 120 ml of water after meals. The patients remained recumbent, not smoking or consuming any food or beverage, during the course of the visit. Blood samples were collected for estimation of blood glucose, insulin and triglyceride levels at stipulated time points (Baseline at 0 min and post-meal at 30, 60, 120, and 180 min) as per schedule of assessments, after the meal had been consumed.

The study was approved by the Ethics Committee of the institution. All the patients provided written informed consent to participate in the study. The study was performed in accordance with the current version of the declaration of Helsinki and in

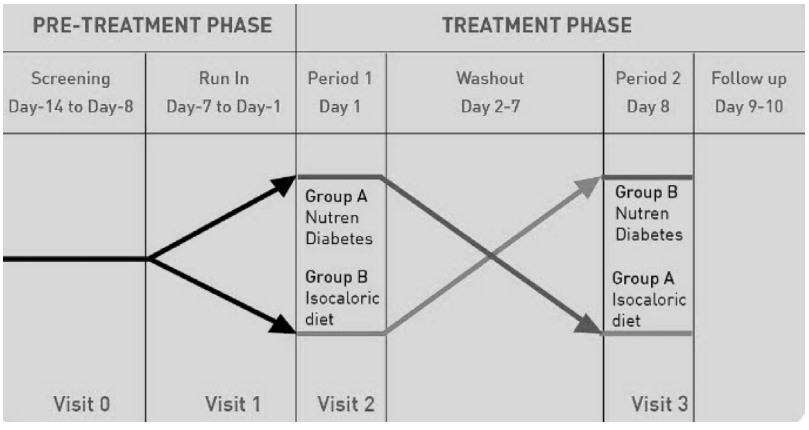

Fig. 1. The study design.