Contents available at ScienceDirect

Diabetes Research and Clinical Practice

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

International Diabetes Federation

Glycemic load, exercise, and monitoring blood glucose (GEM): A paradigm shift in the treatment of type 2 diabetes mellitus

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ARTICLE INFO

Article history:
Received 23 July 2015
Received in revised form
1 September 2015
Accepted 14 October 2015
Available online 21 October 2015

Keywords:
Type 2 diabetes mellitus
Glycemic load
Exercise
Physical activities
Self-monitoring of blood glucose
Postprandial blood glucose

ABSTRACT

Aims: This preliminary RCT investigated whether an integrated lifestyle modification program that focuses on reducing postprandial blood glucose through replacing high with low glycemic load foods and increasing routine physical activities guided by systematic self-monitoring of blood glucose (GEM) could improve metabolic control of adults with type 2 diabetes mellitus, without compromising other physiological parameters.

Methods: Forty-seven adults (mean age 55.3 years) who were diagnosed with type 2 diabetes mellitus for less than 5 years (mean 2.1 years), had HbA1c ≥7% (mean 8.4%) and were not taking blood glucose lowering medications, were randomized to routine care or five 1-h instructional sessions of GEM. Assessments at baseline and 6 months included a physical exam, metabolic and lipid panels, and psychological questionnaires.

Results: The GEM intervention led to significant improvements in HbA1c (decreasing from 8.4 to 7.4% [69–57 mmol/mol] compared with 8.3 to 8.3% [68–68 mmol/mol] for routine care; Interaction $p < .01$) and psychological functioning without compromising other physiological parameters.

Conclusions: Consistent with a patient-centered approach, GEM appears to be an effective lifestyle modification option for adults recently diagnosed with type 2 diabetes mellitus.

1. Introduction

In 2012, the American Diabetes Association (*ADA*) and the European Association for the Study of Diabetes [1] recommended lifestyle modification (LM) as the sole initial treatment for type 2 diabetes mellitus when diagnostic glycosylated hemoglobin (*HbA1c*) is ≤7.5%. Specifically: ''Weight reduction, achieved through dietary means alone or with adjunctive medical or surgical intervention,

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http://dx.doi.org/10.1016/j.diabres.2015.10.021
0168-8227/

improves glycemic control and other cardiovascular risk factors. Modest weight loss (5–10%) contributes meaningfully to achieving improved glucose control ... Foods high in fiber (such as vegetables, fruits, whole grains, and legumes), low-fat dairy products, and fresh fish should be emphasized. High-energy foods, including those rich in saturated fats, and sweet desserts and snacks should be eaten less frequently and in lower amounts ... As much physical activity as possible should be promoted, aiming for at least 150 min/week of moderate activity, including aerobic, resistance, and flexibility training.''. Thus, the ADA recommends weight loss, less consumption of high-energy foods, and at least 150 min/week of moderate physical activity. It does not specify the role of self-monitoring of blood glucose (SMBG) in the management of type 2 diabetes mellitus [2].

Consistent with the ADA recommendations, a major NIH-funded, multi-center trial (Look AHEAD) [3] randomized 5145 overweight adults with poorly controlled type 2 diabetes mellitus to either 42 sessions of an intensive lifestyle modification intervention promoting weight loss through decreased caloric intake and increased exercise or to a diabetes support group. The weight loss group experienced an 8% reduction in weight and a 0.64% reduction in HbA1c, both significantly greater than the support group.

Since the conclusion of the Look AHEAD project, several investigations have focused on specific diets, exercise, and blood glucose (BG) monitoring strategies. Our review of this literature [7] suggests an optimal LM program should emphasize a low glycemic load (GL) diet [8], an exercise program combining aerobic and strength activities, and structured SMBG [2]. To the authors' knowledge, an integrated combination of these three approaches has not been published. Therefore, we have devised a program called the Glycemic load, Exercise, and Monitoring blood glucose program (GEM) that incorporates these strategies.

This represents a paradigm shift from conventional approaches in that GEM:

1. Focuses on reducing postprandial BG elevations, not weight loss.
2. Emphasizes avoidance of high GL foods, not restriction of calories or macronutrients.
3. Encourages eating a variety of available, culturally appropriate, affordable foods that do not produce large elevations in BG, rather than focusing on a specific diet.
4. Recommends increasing physical activities during one's daily routine as opposed to following a structured exercise program.
5. Relies heavily on systematic BG monitoring to [4–6]:
   a. *Educate* individuals about their routine foods that significantly raise their BG levels and therefore should be avoided (e.g., banana, energy bars, corn), about familiar and new foods that do not significantly impact their BG and therefore should be encouraged, and about types of physical activities (plus the timing and duration during the day) that promote lowering BG.
   b. *Motivate* individuals to repeat choices that led to desired BG levels and avoid choices that led to personally unacceptably high BG levels.
   c. *Activate* individuals to eat foods and engage in physical activities based upon selected BG parameters.

This study used a randomized, 2 between (GEM vs. Routine Care [RC]) × 2 within (0- and 6-month assessments) design to test the primary hypothesis that GEM would lower HbA1c more than RC of adults with type 2 diabetes mellitus diagnosed within the past 5 years. The secondary hypotheses were that GEM would lead to more frequent SMBG, more physical activities, and ingestion of fewer high GL foods than would occur with RC. Ancillary benefits of better psychological functioning without worsening hyperlipidemia were also expected. The study was approved by the University of Virginia Institutional Review Board for Health Sciences Research.

2. Subjects, materials and methods

The general public was informed of the project through newspaper, Internet, and radio announcements, and physician referrals. Forty-seven individuals who satisfied the inclusion/exclusion criteria were consented. Given that enrollment was ongoing, three individuals who completed RC were subsequently crossed over to the GEM group. Inclusion criteria were: (1) Diagnosed with type 2 diabetes mellitus within the past 5 years, (2) Age >24 and <80 years, (3) HbA1c ≥7.0%, (4) Approval of primary care physician to participate. Exclusion criteria were: (1) Currently using, or used within the last 3 months, medications that directly lower BG (e.g., insulin, sulfonylureas, glinides; note that patients were allowed to take medications like metformin that did not directly lower BG and lead to hypoglycemia), (2) Currently using, or used within the last 3 months, thiazide diuretics at doses above HCTZ 25 mg or equivalent, or loop diuretics above furosemide 20 mg or equivalent, (3) Currently pregnant or contemplating pregnancy in the coming year, (4) Currently using, or used within the last 3 months, medications that impede weight loss (e.g., prednisone), (5) Having conditions that preclude increasing physical activities (e.g., severe neuropathy, active cardiovascular disease, emphysema, osteoarthritis, stroke), (6) Undergoing treatment for cancer, (7) History of lactic acidosis, (8) Diagnosed with renal impairment.

Five subjects were excluded because baseline HbA1c was <7%, one person dropped out after electing gastric bypass surgery, and two were lost to follow-up. Two of the dropouts were from RC and one was from GEM. This resulted in 21 GEM and 18 RC participants whose pre–post-data were analyzed. The final sample consisted of 18 men and 21 women, with a mean age of 55.3 ± 9.9 years, mean type 2 diabetes mellitus duration of 2.1 ± 1.7 years, mean HbA1c of 8.4 [69 mmol/mol] ± 1.2%, and a mean BMI of 37.9 ± 10. Following randomization to GEM or RC respectively, 29% and 28% were not taking diabetes medication, 38% and 56% were taking one medication (primarily Metformin), 19% and 16% were taking two medications, and 14% and 0% were taking three diabetic medicines.

2.1. Overview

Interested individuals were initially screened over the telephone and informed of study requirements. Their treating physician provided a letter affirming the patient met the