Can J Diabetes xxx (2017) 1–5

Contents lists available at ScienceDirect

Canadian Journal of Diabetes

journal homepage: www.canadianjournalofdiabetes.com

Original Research

Effects on Diabetes Medications, Weight and A1C Among Patients with Obesity and Diabetes: 6-month Observations From a Full Meal Replacement, Low-Calorie Diet Weight Management Program

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ARTICLE INFO

Article history:
Received 24 January 2017
Received in revised form
12 March 2017
Accepted 15 March 2017

Keywords:
diabetes
low-calorie diet
meal replacement
medication changes
weight loss

ABSTRACT

Objectives: A 6-month weight-management program with full meal replacement, low-calorie diet (full MR-LCD) (900 kcal/day for 6 to 12 weeks) follows a protocol for patients with diabetes for decreasing or discontinuing weight-gaining diabetes medications first (Group WG) and then titrating weight-neutral medications (Group WN).
Methods: This is a retrospective cohort study (1992 to 2009) of weight, glycemic control and diabetes medications changes in 317 patients with obesity and type 2 diabetes who were taking medications.
Results: Group WG and Group WN were similar at baseline, except that glycated hemoglobin (A1C) levels were significantly lower in Group WN (7.5% vs. 6.6%; p<0.001). At 6 months, both groups had lost 16% of their weight, and the decreases or discontinuations of medications were 92.1% sulfonureas, 86.5% insulins, 78.8% thiazolidinediones, 77.8% alpha-glucosidase inhibitors, 50% meglitinides, 33.3% dipeptidyl peptidase-4 (DPP-4) inhibitors and 32.8% metformin. At 6 months, compared with baseline, A1C levels improved in Group WG and Group WN (6-month A1C levels 6.7% and 5.8%, respectively; p<0.0001), and Group WN had significantly better A1C levels than Group WG. At 6 months, 30% of patients were no longer taking diabetes medications and had significantly better percentages of weight loss compared with those taking medications (18.6% vs. 16%; p=0.002); both groups had improved glycemic control at 6 months (A1C 6.0% vs. A1C 6.6%; NS).
Conclusions: In patients with obesity and type 2 diabetes taking medications, a full MR-LCD program appears to be safe and includes improvement in A1C levels. At 6 months, the percentage of weight loss can be significantly better in patients who no longer require diabetes medications, and A1C levels are best controlled in patients who are on WN medications.

Mots clés :
diabète
régime hypocalorique
substitut de repas
changements de médicaments
perte de poids

RÉSUMÉ

Objectifs : Un programme de prise en charge du poids d'une durée de 6 mois par une substitution complète des repas-régimes hypocaloriques (SR complète-RH) (900 kcal/jour durant 6 à 12 semaines) utilise un protocole destiné aux patients diabétiques pour diminuer ou interrompre les antidiabétiques qui entraînent la prise de poids (groupe PP) et ensuite ajuster la dose des médicaments qui sont sans effet sur le poids (groupe SEP).
Méthodes : Il s'agit d'une étude de cohorte rétrospective (de 1992 à 2009) sur le poids, la régulation de la glycémie et les changements d'antidiabétiques chez 317 patients souffrant d'obésité et de diabète de type 2 qui prenaient des médicaments.

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http://dx.doi.org/10.1016/j.jcjd.2017.03.006

Résultats : Au début, le groupe PP et le groupe SEP avaient des caractéristiques similaires, à l'exception de l'hémoglobine glyquée (A1c) qui était significativement inférieure dans le groupe SEP (7,5 % *vs* 6,6 %; p<0,001). Après 6 mois, les deux groupes avaient perdu 16 % de leur poids; la diminution ou l'interruption des médicaments étaient de 92,1 % pour les sulfonylurées, 86,5 % pour l'insuline, 78,8 % pour les thiazolidinediones, 77,8 % pour les inhibiteurs des alpha-glucosidases, 50 % pour les méglitinides, 33,3 % pour les inhibiteurs de la dipeptidyl peptidase-4 (DPP-4) et 32,8 % pour la metformine. Comparativement au début, les concentrations d'A1c après 6 mois s'amélioraient dans le groupe PP et dans le groupe SEP (des concentrations respectives de l'A1c après 6 mois de 6,7 % et de 5,8 %; p<0,0001), quoique le groupe SEP avait des concentrations d'A1c significativement meilleures que le groupe PP. Après 6 mois, 30 % des patients ne prenaient plus d'antidiabétiques et montraient un pourcentage de perte de poids significativement meilleur que ceux qui prenaient des médicaments (18,6 % *vs* 16 %; p=0,002); la régulation de la glycémie s'était améliorée chez les deux groupes après 6 mois (A1c de 6,0 % *vs* A1c de 6,6 %; NS).
Conclusions : Chez les patients souffrant d'obésité et de diabète de type 2 qui prennent des médicaments, un programme de SR complète-RH semble démontrer son innocuité et apporte l'amélioration des concentrations de l'A1c. Après 6 mois, le pourcentage de perte de poids peut être significativement meilleur chez les patients qui n'ont plus besoin d'antidiabétiques, alors que les concentrations d'A1c sont mieux maîtrisées chez les patients qui prennent des médicaments SEP.

Introduction

Obesity and diabetes are strongly associated. Both are chronic diseases that are progressive and difficult to treat. Overweight and obesity constitute an estimated 80% to 90% of persons with type 2 diabetes (1) and, in type 1 diabetes, there has been a 7-fold increase in obesity over 20 years (2). Treatment of obesity in patients with diabetes is further complicated by the fact that some glucose-lowering medications, such as insulin, are associated with weight gain (3,4). Conversely, weight loss improves glycemic control by increasing insulin sensitivity and glucose uptake and reducing hepatic glucose output (4).

Accordingly, achieving normoglycemia in patients with diabetes requires a balance of both weight management and selection of appropriate diabetes medications. In general, the principle of weight reduction is to follow a lower caloric diet that is sustainable (5). In patients with type 2 diabetes, hypoglycemic agents that involve the potential for weight gain may reduce the rate of weight loss (6). Therefore, for management of weight in patients with type 2 diabetes, a balance must be established between sustainable diets and the use of medications for glycemic control.

Meal replacements (MRs) show strong evidence as being a good tool for weight management (7). MRs have been reported in patients with type 2 diabetes and have been shown to produce superior weight loss compared to individualized diet plans. This was observed irrespective of whether it was a partial MR, in which 1 or 2 meals and snacks are replaced by MRs, aiming for a 500 to 1000 daily kcal deficit (8–10), or full MRs, in which all meals are replaced with MRs as low-calorie diets (LCDs), defined as 800 kcals per day or more. The relationship between changes in hypoglycemic medications and weight loss with full MRs have been described previously in a few small cohorts of 8 to 32 patients (11–13). The limitations of these studies include the small sample sizes, the narrow choices of hypoglycemic agents and the severity of the diets which, in 1 study, was 425 kcals per day. The aim of our study was to determine the beneficial effects and changes in hypoglycemic agents within a behavioural program using full MR-LCDs in patients with obesity and diabetes. We hypothesized that in a full MR, medically supervised weight-management program, patients with diabetes would lose weight, require less hypoglycemic medications and have improved glycemic control.

Methods

A retrospective cohort study was conducted in 2744 patients consecutively enrolled between 1992 and 2009 in the CORE program at the Ottawa Hospital Weight Management Clinic (OHWMC) in Ontario, Canada. The study protocol was approved by The Ottawa Hospital Research Ethics Board. The CORE program enrols patients with diagnosed obesity so as to assist in weight management, with the goal of improving long-term health. The CORE program is a year-long, comprehensive, intensive lifestyle behavioural program.

Intervention

The first 6 months (week 1 to week 26) include mandatory weekly group sessions led by a dietitian, behaviour therapist or exercise therapist and, in the last 6 months (weeks 27 to 52), patients are offered monthly support sessions, which they can choose to access. All patients receive OPTIFAST ®900 as full meal replacements starting at week 2. Patients consume 4 MR shakes per day for a total of 900 kcal per day, a regimen that is high in proteins (90g/day) and moderate in carbohydrates (67 g/day). Patients with initial body mass indexes (BMIs) of 33 kg/m^2 or higher commit to 12 weeks of full MRs, while patients with initial BMIs below 33 start with 6 weeks of full MRs and the option to increase to up to 12 weeks of full MRs. Once patients have completed their full MR regimen, there is a 5-week transition period to regular food, typically followed by a maintenance diet, as determined in a one-on-one dietitian counselling session.

Clinical care

During the first 6 months at the OHWMC, physician visits occur weekly, and medications are adjusted as needed. After 6 months, patients may attend monthly support groups, but follow up with the OHWMC physician is booked as needed with respect to weight management. Patients return to their primary care physicians at 6 months for ongoing regular medical monitoring, including management of diabetes medications.

For patients with type 2 diabetes who are on full MR, the clinic protocol is first to reduce weight-gaining medications (Group WG). Within Group WG, priority is given to decreasing medications that have hypoglycemic effects and, subsequently, other weight-gaining medications. Finally, weight-neutral medications (Group WN) may be reduced if clinically indicated. Group WG includes patients taking insulin, sulfonureas (SUs), thiazolidinediones (TZDs) and/or meglitinides. Patients in Group WG may also be on weight-neutral medications. Group WN is composed of patients taking solely metformin and alpha-glucosidase inhibitors (AGIs). The data collected for this study predates the availability of glucagon-like peptide-1 (GLP-1) agonists and sodium-glucose co-transporter 2 (SGLT2) inhibitors in Canada. Dipeptidyl peptidase-4 (DPP-4) inhibitors had just been introduced in Canada, and the rare patients who