

The effect of Extend Bar[®] containing uncooked cornstarch on night-time glycemic excursion in suspects with type 2 diabetes

Maryellen Dyer-Parziale *

Casa Pacifica Medical Clinic, 1722 S Lewis Rd, Camarillo, CA 93012, USA

Received 23 November 1999; received in revised form 24 April 2000; accepted 15 May 2000

Abstract

The objective of this study was to determine the effects of ingesting a snack bar containing uncooked cornstarch (Extend Bar[®], Clinical Products, Limited, Key Biscayne, FL) on nocturnal glycemic excursion in 28 adults (ages 22-78 years) with type 2 diabetes mellitus (mean HbA1c $8.21 \pm 1.28\%$). Thirteen subjects were treated with oral agents, eight with a combination of insulin and oral agents, and seven with insulin alone. Subjects ingested the study bar (Extend Bar[®], containing 30 g of total carbohydrate, including 5 g of uncooked cornstarch, 3 g protein, and 3 g fat) for three evenings followed by a placebo bar for 3 evenings (30 g of total carbohydrate, 3 g protein, and 3 g fat), or vice versa. Pre-snack before bedtime, midnight and before breakfast finger stick blood glucose levels were compared to determine the incidence of hypoglycemia (< 60 mg/dl), hyperglycemia (> 250 mg/dl), and to calculate any differences in the group's mean blood glucose levels when ingesting the study versus the placebo bar. There were no episodes of hypoglycemia or hyperglycemia. The mean blood glucose levels pre-snack at bedtime were nearly identical (Extend Bar[®] value 117.5 ± 45.6 mg/dl; placebo bar value 117.3 ± 40.0 mg/dl; $P = 0.977$), and lower at midnight and before breakfast on the Extend Bar[®] nights compared to the placebo bar nights (Extend Bar[®], midnight value 127.9 ± 31.0 mg/dl; placebo bar midnight value 148.2 ± 32.1 mg/dl; $P = 0.0001$; Extend Bar[®] breakfast value 114.2 ± 15.8 mg/dl; placebo bar breakfast value 158.49 ± 30.3 mg/dl; $P < 0.0001$). These data suggest that ingesting Extend Bar[®] containing uncooked cornstarch as the nighttime snack may be an effective strategy to lessen the frequency of nocturnal and morning hyperglycemia in subjects with type 2 diabetes. © 2001 Elsevier Science Ireland Ltd. All rights reserved.

Keywords: Extend Bar[®]; Cornstarch; Hyperglycemia; Hypoglycemia; Type 2 diabetes

1. Introduction

Controlling glycemic excursion in subjects with type 2 diabetes mellitus is an important goal to limit the devastating long-term complications of this disease [1,2]. One strategy, which has been shown to effectively limit glycemic excursion in patients with type 1 diabetes has been the use of a snack bar containing uncooked cornstarch ([3-5]) - a complex carbohydrate, which is slowly absorbed from the gastrointestinal track over a 6-9 h period [6,7]. Kaufman et al. showed a decrease in the incidence of hypoglycemia at midnight and in the morning after the ingestion of a snack bar containing uncooked cornstarch compared to a placebo bar with the same grams of carbohydrate ([3-5]). Of equal importance, particularly in the management of hyperglycemia prone patients with type 2 diabetes, there was no increase in observed hyperglycemia after ingesting the cornstarch snack bar.

The present study was undertaken to determine if a snack bar (Extend Bar[®], Clinical Products, Limited, Key Biscayne, FL) containing 5 g of uncooked cornstarch could decrease the incidence of hyperglycemia at midnight, 2-3 h post-ingestion, and the next morning, 8-9 h post-ingestion, in adults with type 2 diabetes. Subjects were chosen for participation regardless of whether they were receiving oral hypoglycemic agents, insulin or combination therapy.

2. Materials and methods

Twenty-eight subjects (11 men and 17 women) with type 2 diabetes followed in Casa Pacifica Medical Clinic in Ventura, CA were chosen for this study after informed consent was obtained. The mean age of the subjects was 61.9 ± 14.5 years (range 23 months-78 years), the mean diabetes duration was 49.7 ± 53.6 months (range 2 months-20 years) and the mean HbA1c was $8.27 \pm 1.3\%$ (range 6.7 - 10.81/0). There were 13 subjects treated with oral agents, 8 with insulin and 7 with combination therapy. They routinely had a pre-bedtime snack.

Table 1
Content of Extend Bar versus the Placebo Bar^a

	Extend Bar	Placebo Bar
Calories	160	160
Total carbohydrate (g)	31	31
Uncooked cornstarch (g)	5	0
Protein (g)	3	3
Total fat (g)	3	3
Monounsaturated fat (g)	1	1
Saturated fat (g)	1.5	1.5
Cholesterol (mg)	0	0

^a Ingredients: Rice flour, chocolate chips (maltitol, unsweetened chocolate, cocoa butter, soy lecithin, natural flavor), fructose, maltitol syrup, cornstarch (Extend Bar only), soy protein isolate, rice bran, honey, soybean oil, malt, salt, natural flavor.

The 28 study subjects with type 2 diabetes were randomly assigned to ingest Extend Bar[®] for 3 evenings followed by a placebo bar for three evenings, or vice versa. The content of the two 160 kcal bars are given in Table 1. The subjects were blinded as to the type of bar they ingested and were instructed to follow their regular diabetes routine during the study period, including having a usual dinner on all study nights. Pre-snack before bedtime, midnight and before breakfast finger stick blood glucose levels were

obtained with the patient's home glucose meter and results were recorded by the subject on a data sheet. Results from these determinations were compared to determine the incidence of hypoglycemia (number of glucose readings < 60 mg/dl), hyperglycemia (number of glucose readings > 250 mg/dl), and to calculate any differences in the group's mean blood glucose levels at the 3 evaluation times when ingesting the cornstarch snack bar versus the placebo bar. Statistical analysis was done with student's t-test.

3. Results

There were no episodes of hypoglycemia or hyperglycemia pre-snack before bedtime, at midnight or before breakfast during the study period. As shown in Fig. 1, the mean blood glucose levels pre-snack at bedtime were nearly identical. However, the mean blood glucose levels were significantly lower at midnight and before breakfast on the

nights that the Extend Bar[®] was ingested compared to the placebo bar. There were no significant differences in blood glucose levels by type of diabetes treatment regimen. The bars were well tolerated with no episodes of gastrointestinal side effects.

4. Conclusions

These data suggest that adult subjects with type 2 diabetes had significant reduction in midnight and fasting blood glucose levels on the nights that the Extend Bar[®], containing uncooked cornstarch, was ingested compared to a placebo bar of equal carbohydrate, protein and fat content but without uncooked cornstarch. This occurred regardless of the treatment regimen followed, with subjects on oral agents, insulin and both showing reduction in fasting and midnight blood glucose levels. It appears that ingestion of Extend Bar[®] as the nighttime snack before bed may be an effective strategy to lesson the frequency of nocturnal and morning hyperglycemia in subjects with type 2 diabetes without increasing the risk of hypoglycemic events.

Uncooked cornstarch is a complex carbohydrate composed of 27% of the linear chain dextrose polymer amylose and 73% of the branched chain dextrose polymer amylopectin [5]. Uncooked cornstarch is converted into maltose and other very small glucose polymers in the small intestine by the hydrolytic effect of pancreatic amylase. Intestinal epithelial enzymes allow for further hydrolysis and the slow absorption that occurs into the portal circulation over at least a 6 h period [7]. As a result of this slow hydrolysis and absorption, and perhaps as a result of mixing the carbohydrate with fat and protein [5], glucose entry into the blood stream may be delayed even further, extending over a 6 h period. This helps avoid extremes of glycemic excursion and reduces hyperglycemic and hypoglycemic episodes.

The study showed that ingesting Extend Bar[®] allowed for a significant reduction in fasting blood glucose levels. Reduction in fasting glycemia is the goal of the intensive management of type 2 diabetes. As outlined in the algorithms developed by the UKPDS [2], the goal of therapy for type 2 diabetes is to achieve a fasting glucose level between 110-120 mg/dL. That goal was achieved in this study for the subjects when they ingested Extend Bar[®]. This would suggest that Extend Bar[®] should be a useful adjunct to the diabetes regimen for subjects with type 2 diabetes on insulin, oral agents, or both wishing to eat a snack before bedtime.

References

[1] The Diabetes Control and Complication Trial Research Group, The effect of intensive diabetes management on the development and progression of long-term complications in insulin dependent diabetes mellitus. The diabetes control and complication trial, N. Engl. J. Med. 329 (1993) 977-987.

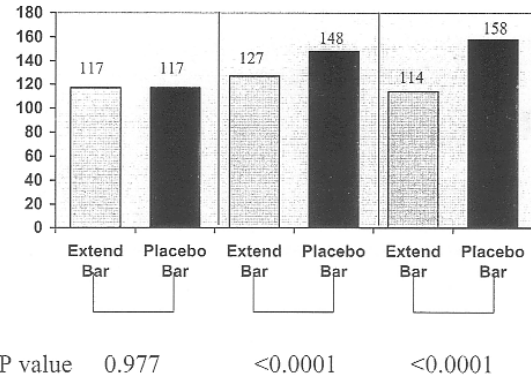


Fig. 1. Comparisons between blood glucose levels (mg/dl) pre-snack before bedtime, midnight, and before breakfast with Extend Bar versus Placebo bar.

[2] UKPDS Group, Lancet 352 (1998) 837.

[3] F.R. Kaufman, S. Devgan, Use of uncooked cornstarch to avert nocturnal hypoglycemia in children and adolescents with type I diabetes. J. Diabetes Complications 10 (1996) 84-87.

[4] F.R. Kaufman, M. Halvorson, N.D. Kaufman, A randomized, blinded trial of uncooked cornstarch to diminish nocturnal hypoglycemia at diabetes camp, Diabetes Res. Clin. Pract. 30 (1995) 205-209.

[5] F.R. Kaufman, M. Halvorson, N.D. Kaufman, Evaluation of a snack bar containing uncooked cornstarch in subjects with diabetes, Diabetes Res. Clin. Pract. 35 (1997) 27-33.

[6] Y.-T. Chen, M. Cornblath, J.B. Sidbury, Cornstarch therapy in type I glycogen-storage disease, N. Engl. J. Med. 310 (1984) 1721-1725

[7] R. Lozano, S.A. Chalew, A.A. Kowarski, Cornstarch ingestion after oral glucose loading: Effect on glucose concentrations, hormone response, and symptoms in patients with postprandial hypoglycemia syndromes, Am. J. Clin. Nutr. 52 (1990) 667-670.