

Thesis Title Effects of Dietary Therapy on Protein-energy Status, Carbohydrate Metabolism, and Lipid Status in Subjects With Impaired Glucose Tolerance and Patients With Non-insulin-dependent Diabetes Mellitus

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ABSTRACT

The purpose of this study was to evaluate the efficacy of dietary therapy on protein-energy status, carbohydrate metabolism, and lipid status as well as its safety in 10 subjects with impaired glucose tolerance (IGT) consisting of 4 men and 6 women and 7 patients with non-insulin-dependent diabetes mellitus (NIDDM) consisting of 2 men and 5 women. Their ages ranged from 48 to 76 years. The study consisted of 5 periods; each period lasted for 2 weeks. During week -2 to week 0, the subjects consumed their habitual diet at their homes and were instructed to keep daily dietary record for dietary assessment. During weeks 0-2, the subjects consumed their habitual diet at their homes and were instructed to consume 40 g of Gen-Formula[®] twice daily as a snack at 10 am and 3 pm;

Gen-Formula[®] is a nutritionally complete enteral formula manufactured in powder form. Each 40 g of Gen-Formula[®] provide 180.9 kcal, 6.8 g protein, 6.1 g fat, and 24.7 g carbohydrate. During weeks 3-4, the subjects consumed the assigned diet prepared by dietitians and 80 g of Gen-Formula[®] daily. The dietary energy distribution of the assigned diet consisted of 15% protein-, 30% fat-, and 55% carbohydrate-calories. Soybean oil was used as the sole source of cooking oil providing 20% of total calories. Energy intake in each subject during weeks 3-4 was based on her (his) mean energy intake during weeks -2 to 0 plus 10%. During this period, they were taught how to prepare the assigned diet. During weeks 5-6, the subjects consumed the assigned diet prepared by themselves at home plus 80 g of Gen-Formula[®] daily. During weeks 7-8, subjects consumed the assigned diet prepared by themselves at home without Gen-Formula[®] as supplementation. 5 out of 7 patients with NIDDM were treated with sulfonylurea prior to the study; the dosage of the drug in each patient was maintained throughout the study.

The results show that energy intakes of 1,562-1,858 kcal/d with dietary fat energy of 28.6-29.8% of total calories were effective in lowering body weight in subjects with IGT with mean BMI of 22.39 kg/m² but it did not change their abdominal obesity. The non-significant decrease in body weight in NIDDM could be explained by significantly higher BMI in NIDDM than that in IGT at week 0 and higher intakes of energy and fat in NIDDM than those in IGT at the corresponding periods during weeks 0-8.

The main source of carbohydrate in the assigned diet and Gen-Formula[®] were complex carbohydrate. Their beneficial effect on glycemic

control was evidenced by the significantly lower fasting blood glucose (FBG) level at week 4 and HbA_{1C} level at week 6 than those at weeks 0 and 2, respectively, in IGT as well as significantly lower FBG levels at weeks 4 and 6 and HbA_{1C} level at week 8 than those at week 2 in NIDDM. The lack of significant difference in FBG level between weeks 6 or 8 and weeks 0 and 2 implied the imprecise preparation of the assigned diet by subjects at their homes.

Out of 10 subjects with IGT at week 0, 1 had elevated serum total cholesterol (TC) level of 5.30 mmol/L only, 6 had serum TC \geq 5.17 and LDL-C \geq 3.36 mmol/L, 1 had serum TC \geq 5.17, LDL-C \geq 3.36 and triglyceride (TG) \geq 2.26 mmol/L, 1 had serum TC \geq 5.17 and serum TG \geq 2.26 mmol/L and 1 had serum TC \geq 5.17, TG \geq 2.26 and HDL-C $<$ 0.9 mmol/L. At week 0 out of 7 patients with NIDDM, 4 (57.1%) had serum TC \geq 5.17 and LDL-C \geq 3.36 mmol/L, 1 (14.3%) had serum TC \geq 5.17, TG \geq 2.26, and HDL-C $<$ 0.9 mmol/L, and 2 (28.6%) had TC \geq 5.17 mmol/L only. The latter 2 patients with serum TC \geq 5.17 mmol/L could be classified as normolipidemia because serum TC levels at week 0 in both patients were 5.18 mmol/L.

At week 0 the subjects with IGT had mean total fat intake of 32.5 % of total calories containing 5.91, 8.42, 12.72 and 1.33% of total calories as saturated fatty acids (SFAs), 18:1 n-9, 18:2 n-6, and 18:3 n-3, respectively. During habitual diet and Gen-Formula[®] (wks 0-2), there were no significant changes in their intakes of total fat and the aforementioned FAs. These explain the non-significant changes in their serum lipid, plasma lipoprotein, and serum apoprotein levels. However, during taking the assigned diet and Gen-Formula[®] (weeks 3-6), their fat intakes at weeks

4 and 6 were 28.6 and 29.8% of total calories; their total SFAs intakes significantly reduced to 3.8% and 4.12% of total calories, respectively; at weeks 4 and 6, their 18:1 n-9 intakes significantly reduced to 6.73 and 6.94 % of total calories, respectively; their 18:2 n-6 intakes significantly increased to 12.47 and 12.66 % of total calories, respectively, and their 18:3 n-3 intakes significantly increased to 1.66 and 1.69 % of total calories, respectively. Under such condition their mean serum TC, LDL-C, and apo B levels at weeks 4 and 6 were significantly lower than those at weeks 0 and 2. These findings indicate the requirement for more 18:2 n-6 intake combined with less SFA intake in those already having high 18:2 n-6 intake and low SFA intake in order to lower their serum TC and LDL-C levels. This is supported by the removal of Gen-Formula[®] intake during weeks 7 and 8. There were no significant difference in their mean serum TC and LDL-C levels between weeks 8 and 0 or 2. The mean net decreases in serum TC levels at weeks 4 and 6 from that at week 0 in 10 subjects with IGT were 12.6 and 12.6% whereas the corresponding figures for serum LDL-C levels were 16.0 and 19.1% .

The significant decrease in mean serum LDL-C and apo B levels at week 2 from those at week 0 in 7 patients with NIDDM can be explained by the reduction of their total fat intake from 34.34 % of total calories at week 0 to 32.88 % of total calories at week 2 and significant reduction in their SFA intakes from 8.27 % of total calories at week 0 to 6.17 % of total calories at week 2 together with the increase in their 18:2 n-6 from 10.50 % of total calories at week 0 to 11.53 % of total calories at week 2. Though their mean serum TC and LDL-C levels at weeks 4, 6, and 8 were lower than those at week 0 the differences did not reach the statistical

significance. These could be explained by the significant reduction in their SFA intakes without significantly increases in their 18:2 n-6 intakes during weeks 4-8.

Daily ingestion of the assigned diet and Gen-Formula[®] in 10 subjects with IGT and 7 patients with NIDDM was safe, evidenced by the absence of clinical and laboratory adverse effects. There were no abnormal changes in their hematological parameters of liver and renal function test, serum mineral levels, and carbon dioxide content during receiving the experimental diet.