Comparison of the Effects of Individualized Medical Nutrition Therapy and Consistent Carbohydrate Meal-Planning on Glycemic Control, Energy, and Carbohydrate and Protein Intake in Hospitalized Diabetic Patients: A Randomized Clinical Trial Study

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Abstract

Background: Individualized Medical Nutrition Therapy (IMNT) is recommended as a part of glycemic control in hospitalized diabetic patients. However, it is provided only for a small number of patients. This study aimed to compare the effects of IMNT and Consistent Carbohydrate Meal-Planning (CCMP) on glycemic control, energy, and carbohydrate and protein intake in hospitalized diabetic patients.

Methods: This randomized clinical trial was conducted on 164 hospitalized diabetic patients. The patients were randomly selected from internal wards of Namazi hospital, Shiraz, Iran from September 2016 to October 2017. They were allocated to IMNT or CCMP groups using simple randomization for four days. Blood glucose was measured before each meal and at bedtime. A 24-h food recall was also completed to measure the energy and carbohydrate and protein intake during the study. The data were analyzed using independent sample t-test and repeated measures ANOVA via the SPSS software, version 19.

Results: The results showed a significant decrease in the IMNT group compared to the CCMP group regarding the mean blood glucose level measured prior to breakfast, lunch, dinner, and bedtime during the first, second, third, and fourth days of the study (P=0.025, P=0.030, P=0.002, and P=0.011, respectively). Besides, mean peak and nadir of glucose level (P=0.042 and P=0.036, respectively) and the means of energy, carbohydrate, and protein intake were significantly increased in the IMNT group compared to the CCMP group.

Conclusion: IMNT could help to control the blood glucose. In addition, it could improve energy and nutrients intake, which might play a role in patient recovery.

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Introduction

Medical Nutrition Therapy (MNT) is a well-known part of glycemic control in diabetic outpatients as well as in hospitalized diabetic ones.[1-3] The main goal of MNT in hospitalized diabetic patients is to improve glycemic control. Other goals include providing adequate calories and nutrients to meet the metabolic needs for disease and recovery, preparing meal plans based on individual needs and personal, cultural, religious, and ethnic preferences, and providing nutrition plans for discharge and follow-up.[3-5] MNT consists of nutritional assessment, nutritional intervention, counseling, monitoring nutritional interventions, and evaluation.[6,7] Individualized MNT (IMNT) is recommended to achieve MNT goals.[8] However, due to the limited number of nutrition professionals, it is provided only for a small number of patients in most hospitals.[9] Reduced appetite, increased need for calories and nutrients due to metabolic stress, need for help for eating, and omission of meals for procedures are some barriers affecting nutritional status and glycemic control in hospitalized diabetic patients.[8, 10] Thus, Consistent Carbohydrate Meal-Planning (CCMP) system was established for nutrition management among hospitalized diabetic patients. In this system, the amount of calories is not important, but the content of carbohydrates is consistent from one meal to another and from one day to another.[11, 12] Many hospitals have implemented this system because carbohydrate is mostly effective in the blood glucose level and insulin matching will be easier with the constant amount of carbohydrates consumed each day.[9, 13]

Up to now, no specific diet or percentage of macronutrients has been prescribed for hospitalized diabetic patients.[14] A study showed no difference between two different meal plans regarding the mean blood glucose level and hyperglycemia in diabetic patients admitted to the hospital.[15] However, no randomized clinical trial has compared the effects of different nutritional approaches. Thus, this study aimed to compare the effects of IMNT and CCMP on glycemic control, energy, and carbohydrate and protein intake in hospitalized diabetic patients.

Materials and Methods

Participants

In this study, 170 patients who had ordered a "diabetic diet" in the Hospital Information System (HIS) and were admitted in internal wards of Namazi hospital, Shiraz, Iran were randomly selected from September 2016 to October 2017. Among them, 164 patients were eligible to participate in the study. The internal wards included endocrinology, neurology, nephrology, gastroenterology, cardiology, and general internal. The inclusion criteria were (1) diagnosis of diabetes according to the American Diabetes Association, (2) age > 18 years, and (3) and hospital stay for two days and longer. The exclusion criteria were (1) being in Intensive Care Units (ICUs) and (2) being pregnant or lactating. All participants provided written informed consents prior to the study. The participants were assessed with respect to disease and dietary history, anthropometric and biochemical data, prescribed drugs that influenced glycemic control such as insulin and oral blood glucose-lowering medications, and gastrointestinal symptoms 24 hours after admission. Then, they were randomly allocated to IMNT or CCMP groups by simple randomization, using the table of random numbers.

This study was approved by the Ethics Committee of Shiraz University of Medical Sciences, Shiraz, Iran (IR.SUMS.REC.1395.7) and registered in the Iranian Registry of Clinical Trials (IRCT20171217037916N1). This study was carried out in accordance with the ethical standards of Helsinki.

Diet Plan

In the IMNT group, a dietitian assigned an individualized diet for each participant. The intended diet included three meals and three snacks prepared in the hospital (~50% of energy from carbohydrates, 20% from proteins, and 30% from fat). Harris-Benedict equation with stress factor of 1.1-1.25 and activity factor of 1.1-1.2 was used to calculate the energy requirement. In the CCMP group, food was served based on the CCMP system,[3] including three carbohydrate servings at each meal and two carbohydrate servings in the snacks. This approach is used to provide the hospital diabetic diet. All participants were followed for food intake. A 24-h food recall was also completed to analyze food intake during the four days of the study. The participants were asked not to eat anything except for the hospital food. All participants received nutrition education for diabetic patients and were encouraged to consume the served food.

Outcomes Measurement

The primary outcome measures were changes in the mean, nadir, and peak of blood glucose level during the study period. Blood glucose was measured using GLUCOCARD® 01 glucometer (ARKRAY, Inc.) before each meal and at bedtime.[14, 16] The secondary outcome measures were changes in the mean of energy and carbohydrate and protein intake during the study period.

Statistical Analysis

According to the research by Curll et al.[1)] and considering the significance level of 5% and power of 80%, the sample size, with the probability of dropout, was estimated to be 82 participants per group. After all, 76 participants in each group were analyzed.

Kolmogorov-Smirnov test was used to determine the normality of the data. Continuous variables were presented as mean and standard deviation, while categorical ones were presented as number. Independent sample t-test was used to examine the differences between the two groups concerning nadir and peak of blood glucose, energy, and carbohydrate and protein requirement and intake. Repeated measures ANOVA was also used to compare the two groups with regard to the blood glucose level. Indeed, the 24-h food recalls were analyzed by Nutritionist IV software, version 3.5.2. All analyses were performed using IBM SPSS software, version 19. P<0.05 was considered to be statistically significant.

Results

As shown in Figure 1, in this study, 164 hospitalized diabetic patients were allocated to IMNT and CCMP groups. In the IMNT group, two patients were transferred to ICU, two were discharged, one became NPO, and one expired (n=6). In the CCMP group, one patient was transferred to ICU, one became NPO, two were discharged, and two expired (n=6). Thus, they were omitted from the study. Based on Table 1, the two groups were similar with respect to the baseline demographic and clinical characteristics. The trends of mean blood glucose level in the two groups during the four trial days are illustrated in Figure 2. Accordingly, the mean level of blood glucose measured prior to breakfast (a) followed a descending trend in both groups during the first, second, third, and fourth days of the study, and the descending trend was greater significantly in the IMNT group compared to the CCMP group (P=0.025). Furthermore, a significant decrease was observed in IMNT group compared to the CCMP group regarding the mean level of blood glucose measured prior to lunch (b), dinner (c), and bedtime (d) during the first, second, third, and fourth days of the study (P=0.030, P=0.002, and P=0.011, respectively). As shown in Table 2, the results of t-test revealed a significant reduction in the IMNT group compared to the CCMP group concerning the mean blood glucose level measured at bedtime during the second day (P=0.040), prior to breakfast and dinner during the third day (P=0.024, P=0.021, respectively), and prior to breakfast, lunch, dinner, and bedtime during the fourth day (P=0.037, P=0.012, P=0.003, and P=0.010, respectively) of the study. The results of repeated measures test showed that time had a significant effect on the mean of blood glucose level measured before each meal and at bedtime during the four study days (P<0.001). However, no significant group*time interaction was observed during this period.

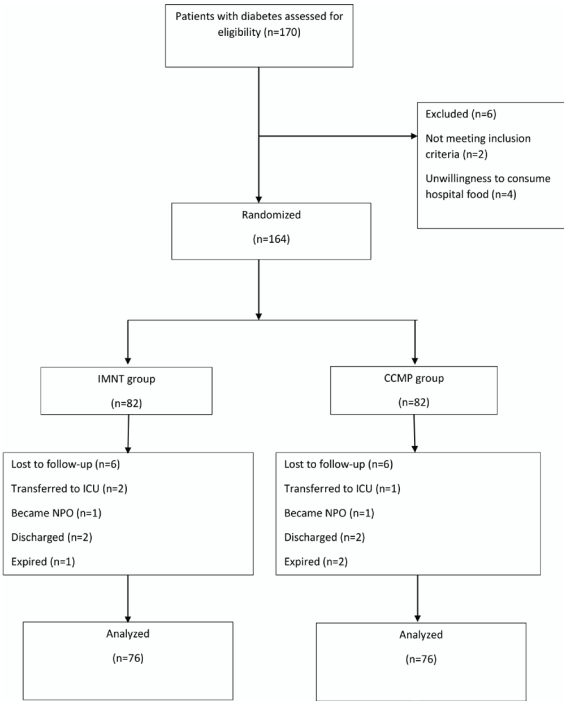

Figure 1: Flow diagram of the study participants

Table 1: Baseline demographic and clinical characteristics of the participants

Variable	IMNT group (n=76)	CCMP group (n=76)	P value
Gender (female/male)	(40/36)	(37/39)	0.626
Age (years)	59.84±12.25	60.25±14.10	0.849
Body mass index (kg/m^2)	24.31±5.06	24.66±5.00	0.673
Disease duration	13.80±4.16	13.27±3.90	0.423
Mean level of blood glucose (mg/dl)	223.94±60.66	226.31±67.99	0.821
Admission ward (n)			0.997
Endocrinology	17	17	
Gastroenterology	2	2	
Neurology	5	6	
General internal	37	34	
Nephrology	7	8	
Cardiology	8	9	
Medications (n)			
Insulin therapy	75	75	
Oral hypoglycemic agents	1	1	

IMNT: Individualized nutrition therapy; CCMP: Consistent carbohydrate meal-planning. Data have been expressed as mean±standard deviation

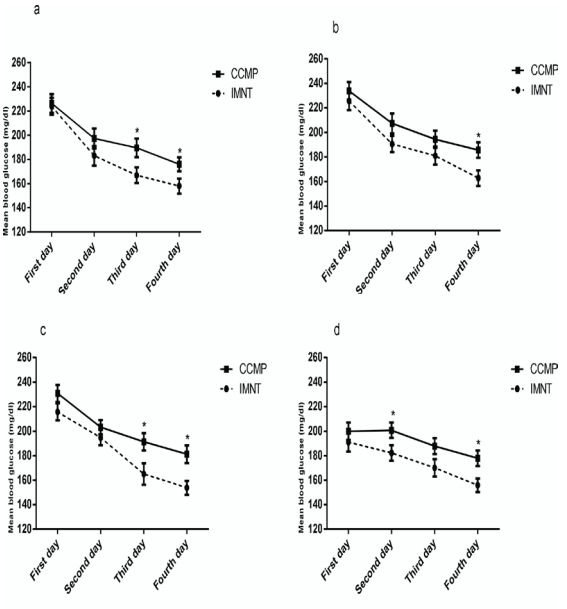

Figure 2: The two groups' mean levels of blood glucose measured prior to breakfast (a), lunch (b), and dinner (c) and at bedtime (d)during the first, second, third, and fourth days.IMNT, individualized nutrition therapy; CCMP, consistent carbohydrate meal-planning. *P<0.05

In other words, changes in the mean blood glucose level over time were the same in both groups. The results also indicated significant improvement in the mean level of blood glucose over time in the IMNT group compared to the CCMP group.

According to Table 3, a significant difference was found between the two groups regarding the mean peak and nadir of glucose level (P=0.042 and P=0.036, respectively). Besides, the means of energy, carbohydrate, and protein intake were significantly increased in the IMNT group compared to the CCMP group (P<0.001, P=0.033 and P<0.001, respectively).

Discussion

MNT is an important part of diabetic patient care in hospitals that should be done by a dietitian as a member of the medical team.[9] Although medical standards for diabetes care have recommended individualized dietary plan in hospitalized diabetic patients, most hospitals make use of CCMP.[9, 13] Therefore, it is necessary to compare the effects of these two types of diet on glycemic control. The findings of the present study revealed a significant decrease in the IMNT group compared to the CCMP group regarding glycemic control. The mean energy, carbohydrate and protein intake significantly increased in the IMNT group compared to the CCMP group. The only study comparing two standard and patient-controlled CCMP approaches also achieved similar results regarding the nadir blood glucose level, but not concerning the mean and peak of blood glucose level.[15] In contrast, dietary intakes were not evaluated in that study.[15] The current

Table 2: Comparison of the mean levels of blood glucose measured prior to breakfast, lunch, dinner, and bedtime during the four study days

	First day			Second day			Third day			Fourth day			P value[b]		
	IMNT	CCMP	P value[a]	IMNT	CCMP	P value[a]	IMNT	CCMP	P value[a]	IMNT	CCMP	P value[a]	Time	Time*group	Group
Level of blood glucose measured prior to breakfast (mg/dl)	223.94± 60.66	226.31± 67.99	0.821	183.02± 70.82	197.27± 71.95	0.220	166.88± 56.18	189.47± 65.84	0.024	157.92± 54.72	175.89± 50.26	0.037	<0.001	0.441	0.025
Level of blood glucose measured prior to lunch (mg/dl)	225.63± 64.43	233.94± 62.98	0.422	190.56± 57.50	207.39± 70.48	0.109	180.96± 64.50	194.43± 61.99	0.191	162.71± 55.39	185.56± 55.43	0.012	<0.001	0.647	0.030
Level of blood glucose measured prior to dinner (mg/dl)	215.77± 60.54	230.75± 68.53	0.156	194.77± 54.41	203.22± 50.62	0.323	165.05± 76.81	191.36± 61.46	0.021	153.85± 49.36	181.17± 61.92	0.003	<0.001	0.384	0.002
Level of blood glucose measured at bedtime (mg/dl)	190.97± 66.70	199.86± 62.52	0.398	182.26± 55.21	200.73± 54.81	0.040	170.06± 61.92	187.80± 57.11	0.068	155.84± 48.59	177.89± 55.28	0.010	<0.001	0.661	0.011

Data have been expressed as mean± standard deviation. a: t-test analysis; b: repeated measures analysis

Table 3: Comparison of dietary intake and peak and nadir of blood glucose level in the two groups during the study period

Group Variable	IMNT group (n=76)	CCMP group (n=76)	P value
Energy requirement (Kcal)	1918.42±239.36	1904.52±209.75	0.704
Energy intake (Kcal)	1830.16±251.32	1669.97±261.11	<0.001
Carbohydrate intake (g)	231.46±45.83	217.24±35.08	0.033
Protein intake (g)	87.90±19.95	67.25±14.17	<0.001
Peak blood glucose level (mg/dl)	281.76±55.31	299.43±50.77	0.042
Nadir blood glucose level (mg/dl)	95.01±33.04	106.68±35.04	0.036

IMNT: Individualized nutrition therapy; CCMP: Consistent carbohydrate meal-planning. Data have been expressed as mean±standard deviation

study results revealed a significant difference between the two groups regarding the carbohydrate intake. The possible mechanism that mediates more improvement in the IMNT group could be justified by the link between glycemic control and carbohydrates intake. In this way, glycemic control is initially affected by carbohydrates intake and the total amount of carbohydrates ingested; also, inadequate intake of food and carbohydrates can lead to hypoglycemia.[3, 9, 15]

The findings of the present study revealed that energy and protein intake significantly increased in the IMNT group compared to the CCMP group during the study. In the same line, one study on malnourished hospitalized patients with heart failure showed that the individualized nutritional intervention was effective in optimizing the energy and protein intake, which allowed the patients to cope with the disease and have better prognosis, eventually reducing the risk of death.[17] In another study, individual nutritional counseling in hospitalized undernourished patients increased the quality of life in addition to energy and protein intake.[18] Under-nutrition has been reported in 20-60% of hospitalized patients.[19-21] Two other studies on hospitalized patients also showed that nutritional counseling and intervention met the energy and protein requirements of hospitalized patients.[22, 23] However, none of these studies has specifically addressed the effects of dietary intervention in diabetic patients with the aim of influencing glycemic control.[17, 18, 22, 23]

The limitations of this study included its short duration, use of a 24-h food recall to estimate the amount of intake, and possibility of consumption underestimation. Additionally, there was no tool to measure the food intake outside the hospital menu. Satisfaction rate, an important item in relation to hospitalized patients, was not measured as well.

Conclusion

The study results indicated greater improvement in glycemic control after IMNT compared with CCMP in hospitalized diabetic patients. In addition to glycemic control, IMNT aims to meet the patients' metabolic needs, thereby helping them to recover from the illness, and to reduce the duration of hospitalization and its complications by providing adequate calories and nutrients needed for diabetic patients.

In this study, no follow-up period was considered after the four intervention days, which can be taken into account in further research.

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Conflict of Interest: None declared.

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