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Original Article

Randomized Control Trial of Delivery of Diabetic Meals as an Educational Tool in Japanese Patients with Type 2 Diabetes Mellitus

Saeko IMAI†[1], Mikuko MATSUDA[1,2], Chikako TOGAWA[2], Kayoko OYABU[3], Tatsushi KOMATSU[4], Onkoo RHEE[5], Shizuo KAJIYAMA[2]

[1]Department of Clinical Nutrition, Faculty of Comprehensive Rehabilitation, Osaka Prefecture University, 3-7-30, Habikino, Habikino, Osaka 583-8555, Japan ; [2]Kajiyama Clinic, 25-1-136, Oiwake-cho, Saiin, Ukyo-ku, Kyoto 615-0035, Japan ; [3]Department of Health Science, Kio University, 4-2-2, Koryo-cho, Kitakatsuragi-gun, Nara 635-0832, Japan ; [4] Faculty of Human Life and Science, Doshisha Women's College of Liberal Arts, Teramachi, Imadegawa, Kamigyo-ku, Kyoto 602-0893, Japan ; [5]Department of Health and Nutritional Science, Nagoya Keizai University, Uchikubo, Inuyama, Aichi 484-8504, Japan

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Abstract

We investigated the effects of diabetic meal delivery for self-management in outpatients with type 2 diabetes for 12 months. A total of 83 outpatients with type 2 diabetes were assigned randomly into three dietary intervention groups: for meal delivery group (group M), 16 diabetic meals were delivered over 4 weeks as an educational tool; diet counseling group (group D), individual dietary counseling by a dietitian every 4 weeks and control group (group C); routine education in every 4 weeks. HbAIC levels decreased from 8.5 ± 1.9% to 7.4 ± 1.0% in fifth month ($p < 0.01$), however, increased to 7.8 ± 1.5% after 12 months in group M (p=0.220). HbAIC levels decreased significantly throughout the 12 month period in group D, from 8.6 ± 1.7% to 7.2 ± 0.9% ($p < 0.01$). On the other hand, there were no change observed in HbAIC in group C from 8.6 ± 2.1% to 8.4 ± 1.0%. HbAIC levels in group M were significantly lower than group C after 1 to 5 months ($p < 0.01$), and they were lower in group D than group C throughout 12 months study period ($p < 0.05$). This study provides the evidence that education by delivery of diabetic meals to outpatients with type 2 diabetes can be effective for achieving glycemic control compared to the control group, but not as effective as individual dietary counseling by a dietitian for 12 months.

1 Introduction

Diabetes is responsible for close to 4 million deaths every year with 250 million people worldwide with diabetes in 2007 and this total is expected to increase to over 380 million people with diabetes by 2025. Each year another 7 million people develop diabetes.[1] The current guidelines recommend a target glycated hemoglobin (HbAIC) levels of 7.0% or less for good glycemic control. People with T2DM are at elevated risk for a number of serious health problems, including cardiovascular disease, blindness, kidney failure, and amputations premature death.[2] After adjustment for other risk factors, an increase of 1% in HbAIC level is associated with an increase of 18% in the risk of cardiovascular events [3], an increase of 12 to 14% in the risk of death, and an increase of 37% in the risk of retinopathy or renal failure.[4,5]

Educating patients can influence behavior, which, in turn, can modify metabolic control, influencing changes in glycemic control, blood pressure, lipid levels, physical activity, body weight, lifestyle and self-monitoring skills. However, there are many patients that have little success in their diet.[6,7] Even if patients could achieve their dietary goals, it is difficult to maintain a proper diet for a long period of time.[8,9] Appropriate education should provide the patient with knowledge and skills that allow the patient to carry out self-care on a routine basis.

To establish an efficient dietary education for diabetes self-management, we devised a diabetic meal as a practical educational tool, providing only 4 dinners per week for 4 weeks to investigate the effects of diabetic meal delivery on

†Corresponding author, E-mail: poooch@rehab.osakafu-u.ac.jp

glycemic control for 12 months in Japanese outpatients with type 2 diabetes mellitus (T2DM).

2 Subjects and Methods

2.1 Patients and dietary intervention

Patients diagnosed T2DM who fulfilled the WHO criteria for diabetes were recruited from outpatients visiting the Kajiyama Clinic between 2004 and 2008. Patients were excluded if they had any significant diseases that were likely to affect the outcome or compliance with this study. The exclusion criteria were as follows: heart failure, renal failure, or serious physical or mental conditions. A total of 83 adults with T2DM who attended the clinic (62.2 ± 11.0 years; means ± SD, range 36-83 years) were assigned into three groups by the stratified randomization method that considered age, gender, and duration of diabetes. Each group received one of the following diabetic interventions.

The diabetic meal delivery group (group M) replaced 4 dinners per week for 4 weeks (total 16 meals) with the diabetic meals to learn the appropriate diet and prepare other meals by patients themselves. The meals were designed for each patient and consisted of 1,200 to 1,800 kcal, 16% protein, 60% carbohydrates, 20-25% fat of calories, and 9 g of salt. The meals were cooked and chilled immediately to 3 °C prior to delivery. The cost of the delivery meal was paid for by a grant and usual clinical examinations were paid by health insurance and the patients themselves. If a patient agreed to participate in the diabetic meal delivery study, the subject had three individual sessions with a dietitian at the start of intervention and after 4 and 12 weeks. The sessions were interactive and included a focus on self-management of type 2 diabetes, especially on diet. The participants were encouraged to measure their body weight and record food.

The individual diet counseling group (group D) involved patients having consultations with a dietitian every 4 weeks. The educational counseling covered such topics as diabetes risk factors, its complications, diet and physical activity. The discussions were individualized and focused on specific individual problems and self-management, mainly relating to diet. The goals and plans were to equip the subjects with skills and knowledge of diet and exercise to initiate behavioral changes. The subjects were encouraged to make easy goals to achieve for themselves by thinking about practical goals such as "to eat vegetables first in each meal, and walk 6,000 steps everyday". The dietitians also addressed coping skills for improving psychosocial functions to aid their behavior change. The patients were also encouraged to measure and record their weight at home before and after intervention.

The control group (group C) involved the patients receiving their usual outpatient management every 4 weeks. At baseline, the control group was given general information about lifestyle and diabetes risk by either a doctor or nurse at every visit. The message was to make changes in dietary habits and increase physical activity.

The dietary state before and after intervention over 6 days per patient in group M and D was obtained using a food record in which calorie intake was calculated by using Eiyokun (Kenpakusya, Tokyo, Japan). The study protocol was shown in Table 1 and approved by the Ethics Committee of the School of Comprehensive Rehabilitation at Osaka Prefecture University and all participants gave written informed consent prior to enrollment in the study. No changes were made to oral blood glucose-lowering agents, antihypertensive and lipid-lowering therapies during the study in all groups.

Table 1 The study protocol

		after intervention			
	before intervention	1-month	2-month	3-month	4 to 12-month
Group M	△○● ◎	△○●	△	△	△
Group D	△○●	△○●	△○	△○	△○
Group C	△	△	△	△	△

Medical examination, blood test △
Dietitian counseling ○
Food record for 5 days ●
Sixteen delivery meals for 4 wks ◎

2.2 Laboratory analysis

Laboratory data, body weight and body mass index (BMI; kg/m^2) were collected for all groups at baseline and every 4 weeks, for all participants who completed the entire program. Fasting blood samples were collected in the morning after an overnight fast from all participants every 4 weeks. HbA1c levels were determined by a latex cohesion method (JCA-BM2250, KYOWA MEDEX, Co., Ltd., Tokyo, Japan). Fasting blood glucose (FBG) levels were examined by the hexokinase method (JCA-BM12, Shino Test, Co., Ltd., Tokyo, Japan). Total cholesterol (T-C) and triglyceride (TG) levels were determined by enzyme assay. HDL cholesterol (HDL-C) levels by a direct method (Labospect 008K, Bio Majesty JCA-BM 8060, JEOL, Ltd., Tokyo, Japan) and LDL cholesterol (LDL-C) levels by an enzymatic method (Bio Majesty JCA-BM 8060, JEOL, Ltd., Tokyo, Japan).

2.3 Statistical analysis

The characteristics of the study participants were calculated and expressed as means ± SD. Statistical analyses were performed using SPSS version 15.0 (SPSS Inc., Chicago, IL). Differences between the three groups in baseline were determined by one-way analysis of variance (ANOVA). The Bonferroni/Dunnett *post hoc test* was used to determine the significance of continuous data and the χ^2-test for significance of the categorical variables. Repeated-measures ANOVA was used to determined the difference between the groups and over time. When a significant difference was found by repeated-measures ANOVA, paired *t*-tests with Bonferroni correction were applied to identify specific differences. A p-value of less than 0.05 was considered statistically significant.

3 Results

The clinical characteristics of the three intervention groups are shown in Table 2. There were no significant differences in the clinical background of the subjects in the three groups with respect to gender, age, body mass index (BMI), diabetes duration, blood pressure, laboratory data, diabetic treatments and energy goals.

Our primary target was glycemic control, as indicated by HbA1c levels. Fig. 1 displays HbA1c results from baseline to 12 months after intervention in the three groups. In group M, HbA1c levels improved from 8.5 ± 1.9% at baseline to 7.9 ± 1.1% immediately after intervention and to 7.4 ± 1.0% in 5 months ($p < 0.01$). However, the HbA1c levels slightly increased to 7.8 ± 1.5% in 12 months ($p = 0.220$). Better results were found for the patients in group D, HbA1c decreased from 8.6 ± 1.7% to 8.2 ± 1.3% ($p < 0.01$) soon after intervention and to 7.2 ± 0.9% at 12 months ($p < 0.01$). In contrast, HbA1c levels did not demonstrate much change in group C from 8.6 ± 2.1% at baseline to 8.4 ± 1.0% at 12 months after intervention. Table 3 shows the changes in laboratory data from baseline to 12 months after intervention in the three groups. FBG levels decreased significantly after 12 months in group D ($p < 0.01$), and demonstrated lower than that in group C after 6 and 12 months ($p < 0.05, p < 0.01$,

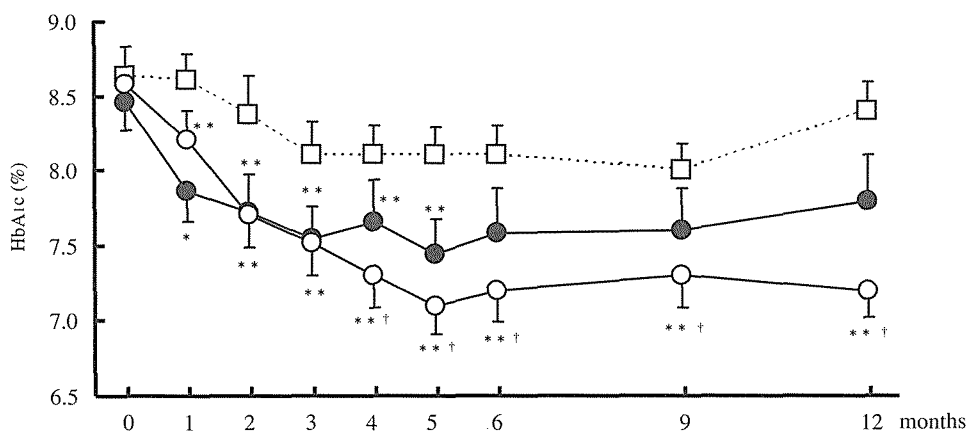

Fig. 1 HbA1c levels after intervention in group M (closed circle), D (opened circle) and C (opened square). Data are means ± SE. Significant difference from the baseline, * $p < 0.05$, ** $p < 0.01$. Group D vs. Group C, † $p < 0.05$.

Table 2 Baseline clinical characteristics of the three study groups

	GroupM (n=27)	Group D (n=29)	Group C (n=27)	P
Gender (males / females)	8 / 19	15/14	13/14	0.207
Age (yrs)	61.0 ± 11.1	62.0 ± 11.2	63.5 ± 11.1	0.720
BMI (kg/m^2)	24.6 ± 5.3	24.4 ± 3.9	24.0 ± 3.4	0.877
Duration of diabetes (yrs)	9.9 ± 8.8	10.7 ± 10.8	12.4 ± 6.8	0.566
Systolic blood pressure (mmHg)	126 ± 14	128 ± 15	133 ± 11	0.220
Diastolic blood pressure (mmHg)	72 ± 7	73 ± 7	73 ± 11	0.776
HbA1c (%)	8.5 ± 1.9	8.6 ± 1.7	8.6 ± 2.1	0.942
Fasting plasma glucose (mg/dl)	165 ± 46	180 ± 69	193 ± 68	0.300
T-C (mg/dl)	212 ± 27	213 ± 33	217 ± 41	0.858
HDL-C (mg/dl)	64 ± 17	59 ± 16	62 ± 16	0.279
LDL-C (mg/dl)	124 ± 25	120 ± 31	128 ± 35	0.599
TG (mg/dl)	134 ± 96	150 ± 87	142 ± 89	0.706
Diabetes treatment:				0.633
Diet only	7	10	6	
Oral hypoglycemic agents	17	13	16	
Oral hypoglycemic agents + Insulin	3	6	5	
Energy goals (kcal)	1,444 ± 178	1,541 ± 208	1,493 ± 175	0.163

Data are means ± SD or n.

respectively). Analysis of the lipid profile results showed an improvement of T-C levels in all three groups after 6 and 12 months of intervention ($p < 0.05$), while the LDL-C levels did not reach statistical significance in all groups. There were no differences observed in BMI or blood pressure during the period in all groups.

Dietary intake decreased significantly after intervention in group M, such as energy intake from 1,700 ± 339kcal to 1,437 ± 330kcal ($p < 0.01$), protein intake from 76 ± 21g to 62 ± 19g ($p < 0.01$), fat intake from 51 ± 18g to 43 ± 19g ($p = 0.087$) and carbohydrate intake from 228 ± 62g to 184 ± 44g ($p < 0.01$). Dietary energy, total protein and carbohydrate intake also decreased significantly in group D, such as 1,736 ± 477kcal to 1,427 ± 200kcal ($p < 0.01$), protein intake from 73 ± 21g to 64 ± 11g ($p < 0.05$), fat intake from 49 ± 20g to 41 ± 7g ($p = 0.056$), carbohydrate intake from 252 ± 76g to 195 ± 24g ($p < 0.01$). On the other hand, daily vegetable intake increased from 268 ± 100g to 408 ± 178g in group M ($p < 0.05$), and from 244 ± 53g to 373 ± 80g in group D after intervention ($p < 0.01$). Dietary intakes before and after intervention did not differ between the two intervention groups.

4 Discussion

In this study, we used the diabetic delivery meals as a dietary educational tool for 4 weeks to encourage patients of T2DM for their self-management. Our results have important clinical implications, kept the QOL of patients, and good glycemic control is considered to be of great benefit in the economic cost.[10] It costs approximately $2,100 a week to stay in hospital for diabetic education, whereas diabetic meal delivery costs only $123 for 16 dinners for 4 weeks, and the improving glucose control reduces the medical costs associated with diabetic complications in the future.[11]

The knowledge learned made it easier for them to maintain a proper diet and resulted the good glycemic control without requiring a stay in hospital. The patients who used the diabetic delivery meals were able to learn

Table 3 Results of laboratory data from baseline to the endpoint in subjects in the three study groups

	Baseline	6-month	12-month
BMI (kg/m^2)			
Group M	24.6 ± 5.3	24.3 ± 5.2	24.7 ± 5.6
Group D	24.4 ± 3.9	23.9 ± 3.9	23.8 ± 3.8
Group C	24.0 ± 3.4	24.0 ± 3.0	24.4 ± 3.4
Systolic blood pressure (mmHg)			
Group M	126 ± 14	126 ± 11	128 ± 8
Group D	128 ± 15	124 ± 13	121 ± 10
Group C	133 ± 11	125 ± 10	125 ± 10
Diastolic blood pressure (mmHg)			
Group M	72 ± 7	72 ± 8	70 ± 8
Group D	71 ± 12	72 ± 9	69 ± 7
Group C	73 ± 11	69 ± 9	68 ± 10
FBG (mg/dl)			
Group M	165 ± 46	160 ± 77	139 ± 40*
Group D	180 ± 69	140 ± 39*†	134 ± 35**††
Group C	194 ± 68	178 ± 56	180 ± 62
T-C (mg/dl)			
Group M	212 ± 27	202 ± 33*	197 ± 37*
Group D	213 ± 33	197 ± 29*	198 ± 34*
Group C	217 ± 41	203 ± 31*	198 ± 39*
HDL-C (mg/dl)			
Group M	64 ± 17	58 ± 11	62 ± 15
Group D	57 ± 16	61 ± 17	59 ± 19
Group C	62 ± 16	60 ± 14	61 ± 13
LDL-C (mg/dl)			
Group M	124 ± 25	124 ± 30	112 ± 31
Group D	120 ± 31	107 ± 28	112 ± 28
Group C	128 ± 35	122 ± 25	116 ± 27
TG (mg/dl)			
Group M	134 ± 96	121 ± 53	114 ± 43
Group D	150 ± 88	141 ± 98	139 ± 77
Group C	142 ± 89	140 ± 74	133 ± 72

Data are means ± SD. Baseline vs after intervention; $^{*}p < 0.05$, $^{**}p < 0.01$.
Group D vs Group C; $^{\dagger}p < 0.05$, $^{\dagger}p < 0.01$.

and experience dietary changes as a result of receiving and eating the diabetic meals as an educational tool soon after intervention. Many were able to evaluate that their daily food portions were too large and therefore decreased the portions of rice or meat, while increasing portions of vegetables and kept the proper diet even after the period of delivery meals. As a result, dietary mean energy intake was reduced 15% and carbohydrate intake decreased 19% after intervention in group M. Mean energy and carbohydrate intake also decreased 18% and 23% respectively after intervention in group D. Additionally, the patients in M and D group received medical data, with the majority showing improved glycemic control soon after intervention, as a consequence of increased self-efficacy. After the experience of the short period of diabetic meal delivery, patients gained dietary skills and knowledge and continued to consume a proper diet.[12]

However, the results of HbA1c levels of the patients who received delivery of diabetic meals after one year did not demonstrate significant improvement, because the HbA1c levels of 30% of the participants in group M had increased after one year of the intervention. On the other hand, the patients in D group showed significant decreased in FBG, HbA1c, and TC. The observed difference in incidence between group D and the group C indicated that the intervention needs to be individual and performed consistently in order to be effective in self-management, especially regarding diet. To ensure good outcomes, post-educational programs that enable consultations regarding diet should be considered individually and initiated at regular intervals by dietitians. However, the lower HbA1c levels at 12 months period in group D might lead to a lower incidence of cardiovascular disease or other complications in T2DM remains to be elucidated. This in turn contributes to better long-term metabolic control which adds to the prevention of chronic complications. This result showed the importance of the counseling given to patients by dietitians and its role is increasing in self-management of dietary regimes.

In conclusion, this study provides the evidence that intervention of delivery of diabetic meals as an educational tool in Japanese patients with T2DM was effective but not as effective as individual diet counseling by dietitians for maintaining glycemic control in 12 months.

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List of abbreviations:

BMI	Body mass index
FBG	Fasting blood glucose
HbA1c	Glycated hemoglobin A1c
HDL-C	High density lipoprotein cholesterol
LDL-C	Low density lipoprotein cholesterol
T-C	Total cholesterol
TG	Triglyceride
T2DM	type 2 diabetes mellitus

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