STUDY OF THE EFFECTS OF THE EDUCATIONAL HOSPITALIZATION FOR DIABETES IMPLEMENTING CRITICAL PATHWAY ON LONG–TERM GLYCEMIC CONTROL

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Abstract
We evaluated the effect of diabetes educational hospitalization utilizing the critical pathway (CP) on long–term glycemic control after discharge in type 2 diabetic patients by comparing changes in HbA1c in 18 patients admitted before CP introduction with those in 18 patients admitted after CP introduction. We also investigated the factors related to worsening of glycemic control after discharge from diabetes educational hospitalization. In the patients admitted before CP introduction, HbA1c had worsened significantly 24 months after discharge whereas HbA1c was unchanged for three years in the patients admitted after CP introduction. Univariate analyses revealed that newly initiated insulin therapy during hospitalization was a protective factor related to worsening of glycemic control at 18 months after discharge. Multivariate linear regression analyses revealed that CP introduction was an independent protective factor related to increase in HbA1c at 12 months after discharge and that increase in body weight at one year after discharge and age were independent facilitating factors related to increase in HbA1c at 18 months after discharge. In conclusion, diabetes educational hospitalization with CP is effective for maintaining stable glycemic control levels after discharge although the various individual factors have effects on glycemic control after discharge.

Key words : educational hospitalization, diabetes, critical pathway

Introduction

The number of diabetic patients in Japan has gradually increased from year to year. According to the National Health and Nutrition Examination Survey by the Ministry of Health, Labour and Welfare in 2007, the number of people who were strongly suspected as having diabetes was approximately 8.9 million and that of people who cannot be denied as having possibility of diabetes was approximately 13.2 million[1]. Furthermore, at the time of survey in 2002, the number of people who were strongly suspected as having diabetes had increased by approximately 500 thousand people since the previous study 1997. Thereafter, in the research in 2007, an increase of approximately 1.5 million was seen. The rate of increase in the latter period was therefore three times, that observed in the earlier years.

In order to maintain the quality of life (QOL) of diabetic patients and suppress medical expenses, patient educa-

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tion and treatment to prevent the development and progression of diabetes complications are important. While there have been remarkable advances in medical science in the treatment of diabetes, there is currently no cure for the disease. In order to prevent the development and progression of the diabetes complications, therefore, diabetic patients must inevitably care for themselves in the long-term. Patient education is essential for helping diabetic patients to understand and correctly manage their disease.

"Critical pathway (CP)" as a means to ensure the quality of medical care and the reduction of health care costs has been introduced to the Japanese medical care system[2]. Advantages of the CP are follows : "guidance can be assured without dropped", "patients and their families can participate in understanding the planning" and "duration of hospitalization can be shortened"[3]. Many facilities have introduced the "educational hospitalization with CP for diabetes". By introducing the CP, the education of diabetic patients is carried out by a medical team consisting of trained nurses, registered dieticians, pharmacists and medical doctors, etc. who play its role according to its function. The usefulness of educational hospitalization with use of CP in order to master correct knowledge about diabetes and to practice self-control has also been reported[4-9].

In Akita University Hospital, education of hospitalized diabetic patients for glycemic control had been implemented as the conventional system. The contents of the educational program were planned and deemed appropriate at the discretion of the attending physician, differed from physician to physician and were not systematically organized. Consequently, we introduced CP into educational hospitalization for diabetes glycemic control in April 2003. We began systematic and unified diabetes education in hospitalization. The period of education is two weeks, during which there is plenty of interaction with teaching doctors, nurses, registered dietitians and pharmacists so that diabetic patients gain fundamental knowledge about controlling their diabetes following discharge.

There are many reports on the effects of educational hospitalization utilizing CP on glycemic control levels after six months or one year[4-9], but reports with a follow-up period of more than one year are limited. Therefore, we evaluated the effect of diabetes educational hospitalization before and after the introduction of CP on changes in levels of glycemic control for 3 years after discharge and the factors which affected changes in long term glycemic control level.

Materials and Methods

Subjects

This study was a retrospective observational study that investigated differences in the effects of educational hospitalization with or without use of CP on subsequent long-term glycemic control at Akita University Hospital. Using the list of hospitalized patients of the diabetes unit, we retrospectively selected the type 2 diabetic patients who had been admitted for diabetes glycemic control in the period before the introduction of CP, from April 2002 to March 2003, and in the period after the introduction of CP, from April 2003 to March 2005. Patients who had been admitted to the diabetes unit for other reasons, such as glycemic control for subsequent surgical procedures, therapy for infections or therapy for exacerbations of diabetes complications, were excluded. Patients who had a follow-up period of more than 12 months after discharge and a glycohemoglobin A1c (HbA1c) measurement at 3, 6 and 12 months after discharge were selected. Consequently, 18 patients admitted before, and 18 patients admitted after introduction of CP, were evaluated.

Table 1 indicates the schedule of a typical course of educational hospitalization for diabetes glycemic control utilizing CP.

Evaluation points

Referring to the medical records of the selected patients, we evaluated the following points retrospectively :

1) Background of patients on admission : age, gender, estimated diabetes duration, diabetes treatment, HbA1c (expressed as National Glycohemoglobin Standardization Program [NGSP] values[10]), body mass index [BMI], with or without diabetes complications (defined as having microangiopathy if a patient had at least one component of retinopathy, nephropathy or neuropathy ; defined as hav-

Table 1. The typical timetable for 2-week diabetes educational hospitalization

	Day 1 (Mon.)	2 (Tue.)	3 (Wed.)	4 (Thu.)	5 (Fri.)	6 (Sat.)	7 (Sun.)	Day 8 (Mon.)	9 (Tue.)	10 (Wed.)	11 (Thu.)	12 (Fri.)	13 (Sat.)	14 (Sun.)
inspection	X-ray Blood sampling Urinalysis Stool ssay	If necessary, Blood sampling, X-ray, Electrocardiogram and Carotid echo												
	Blood glucose monitoring													
	24 h urine collection	measurement of Ccr												
Medication (pharmacists)	Checking the oral medicine							Medication guidance						
Diet (registered dietitians)	Apply for nutritional guidance application	Tutoring in the nutrition		Group guidance in nutrition								Tutoring in the nutrition		
	( ) Kcal diabetic diet													
Exercise	Describes the use of pedometer	Use of pedometer			Video learning									
Observation	Measurement of Height and body weight	Weight measuring before breakfast every morning												
	Measurement of Temperature, Blood pressure and Pulse													
	Observation of the foot													
Descriptions (doctor)			Round							Round	Description of the treatment effect			
Education and instruction	Test of knowledge of diabetes at admission Participate in the class for diabetics	Video learning (Basics of diabetes ①)	Video learning (Basics of diabetes ②)	Video learning (Basics of diabetes ③)	Guidance for Self Monitoring Blood Glucose and Self-injection of insulin			Participate in the class for diabetics	Video learning (Therapy of diabetes ①)	Video learning (Therapy of diabetes ②)	Guidance for Daily life after discharge	Test of knowledge of diabetes at discharge		

ing macroangiopathy if a patient had at least one component of past history of stroke, coronary heart disease or peripheral artery disease), treatment of hypertension and treatment of dyslipidemia

2) The presence of newly initiated insulin therapy during admission
3) Glycemic control levels after discharge (HbA1c values at admission and 3, 6, 12, 18, 24, 30 and 36 months after discharge)
4) Changes in body weight after discharge (one, two, three years after discharge)

Data analyses and statistics

The patients' background characteristics were compared before and after the introduction of CP by Mann-Whitney test or chi-square test. The HbA1c values for each time point of 6, 12, 18, 24, 30 and 36 months after discharge and the value of HbA1c three months after discharge, when the maximal effect of hospitalization on improvement of HbA1c levels had appeared (Table 3), were compared by Friedman test followed by Dunn's procedure as multiple comparisons. In addition, we have defined the patients whose HbA1c levels had worsened by 1.0% or more at 12, 18 or 36 months compared to the value at three months after discharge, as the glycemic control worsening group and the others as the non-worsening group. Then, we have performed the univariate analyses (Mann-Whitney test or chi-square test), comparing patients' background clinical characteristics between the glycemic control worsening group and non-worsening group. Furthermore, to determine the background clinical characteristics that independently contributed to worsening of glycemic control, evaluated by the degrees of changes in HbA1c levels at 12, 18 or 36 months from the value at three months after discharge, we have performed multivariate linear regression analysis (in the step-wise forward method, we used Pe<0.05, Pr=or>0.05 ; the Pe option is the probability of entering a variable ; the Pr option is the probability of removing a variable). Data are shown as means ± SD or otherwise indicated. Values of $P<0.05$ were accepted as indicative of statistical significance. All statistical analyses were conducted using StatFlex ver. 6 software (Artech Co. Osaka, Japan).

Results

1. Clinical characteristics of patients

Table 2 shows the clinical characteristics of the 36 hos-

Table 2. Clinical characteristic of patients

	Before introduction of critical pathway	After introduction of critical pathway
Gender (male / female)	10 / 8	10 / 8
Age (year)	65.1±9.6	60.4±11.1
Duration of diabetes (years)	13.3±10.4	10.6±7.2
Body mass index (kg/m^2)	25.7±4.8	26.7±5.1
Treatment of diabetes at admission diet/OHA/insulin	2 / 12 / 4	1 / 14 / 3
Treatment of diabetes at discharge diet/OHA/insulin	0 / 5 / 13	1 / 6 / 11
Newly insulin initiation	9 (50 %)	8 (44.4%)
HbA1c at admission (%)	9.6±1.4	10.3±1.9
Microangiopathy	13 (72.2%)	11 (61.1%)
Macroangiopathy	6 (33.3%)	3 (16.7%)
Treatment of hypertension	13 (72.2%)	11 (61.1%)
Treatment of dyslipidemia	6 (33.3%)	5 (27.8%)

OHA, oral hypoglycemic agents ; HbA1c, glycohemoglobin A1c. Data are expressed as mean±SD or otherwise indicated.

pitalized patients before and after the introduction of CP. There were no statistically significant differences in clinical characteristics of the patients between two groups. After hospitalization, more than half of the patients had been treated with insulin in both groups (13 patients [72.2%], before CP ; 11 patients [61.1%], after CP). In the majority of the patients, insulin therapy was initiated during hospitalization (9 patients before CP, 8 patients after CP). There were no differences in having or not having one of the components of micro- or macroangiopathy, hypertension treatment or dyslipidemia treatment between groups before and after CP introduction.

2. Changes in HbA1c levels after discharge

Table 3 shows changes in HbA1c levels after discharge. Before introduction of CP, Friedman test revealed significant changes in HbA1c levels during all of 3-12, 3-18, 3-24, 3-30 and 3-36 months after discharge ($P<0.01$), indicating obvious worsening of glycemic control in this group. In particular, HbA1c levels 24, 30 and 36 months after discharge were significantly increased compared to the value at three months after discharge, by Dunn's procedure. In contrast, in the patients admitted after CP introduction, there were no statistically significant changes in HbA1c levels throughout the observed period.

Figure 1 shows changes in increases in HbA1c from the value at three months after discharge both before and after the introduction of CP. In the patients admitted before CP introduction, there were significant changes in the increase in HbA1c from the value at three months after discharge as revealed by Friedman tests, indicating a gradual worsening of glycemic control in this group. In contrast, in the patients admitted after CP introduction, the increase in HbA1c from the value at three months after discharge did not change, indicating that these patients who had received diabetes education with CP had

Table 3. Changes in HbA1c levels with or without the introduction of critical pathway

	Before introduction of CP	After introduction of CP
	HbA1c (%) numbers	HbA1c (%) numbers
admission	9.6 ± 1.4 $N = 18$	10.3 ± 1.9 $N = 18$
3 months after discharge	7.1 ± 0.8 $N=18$	7.6 ± 1.1 $N = 18$
6 months after discharge	7.4 ± 1.1 $N =18$	7.8 ± 1.1 $N = 18$
12 months after discharge	7.8 ± 1.2 $N = 18$	7.7 ± 1.0 $N =18$
18 months after discharge	7.8 ± 1.2 $N = 18$	7.8 ± 1.0 $N =18$
24 months after discharge	8.2 ± 1.1* $N = 17$	7.8 ± 1.0 $N = 18$
30 months after discharge	8.0 ± 1.5* $N = 16$	7.7 ± 0.9 $N = 18$
36 months after discharge	8.1 ± 1.5* $N = 16$	8.2 ± 1.4 $N = 17$

CP, critical pathway. Data are expressed mean±SD or otherwise indicated. Before introduction of CP, Friedman test revealed significant changes in HbA1c levels during 3-12, 3-18, 3-24, 3-30 and 3-36 months after discharge ($P<0.01$). *, $P<0.05$ compared with HbA1c three months after discharge by Dunn's procedure. After introduction of CP, Friedman test revealed no statistically significant changes in HbA1c levels during 3-12, 3-18, 3-24, 3-30 and 3-36 months after discharge.

Table 4. The results of multivariate linear regression analyses to seek the independent factors contributing to the worsening of glycemic control evaluated by the changes in HbA1c from the value at three months after discharge at each time point

	12 months after discharge (N=36)	18 months after discharge (N=36)	36 months after discharge (N=33)
Linear regression analysis with all variables	CP introduction Standard β, −0.3858 P = 0.0485	none	none
Linear regression analysis with forward stepwise method	none	BW increase after 1 year Standard β, +0.3657 P = 0.0263 ; Age Standard β, +0.3472 P = 0.0340	none

CP, critical pathway ; BW, body weight. Independent variables : age, gender, duration of diabetes (years), CP introduction, insulin use at discharge, newly initiation of insulin, HbA1c at admission (%), BMI at admission, BW gain (kg) one year after discharge (at 36 months after discharge, including BW gain two and three years after discharge), having or not micro- macrovascular complications, hypertension treatment, dyslipidemia treatment.

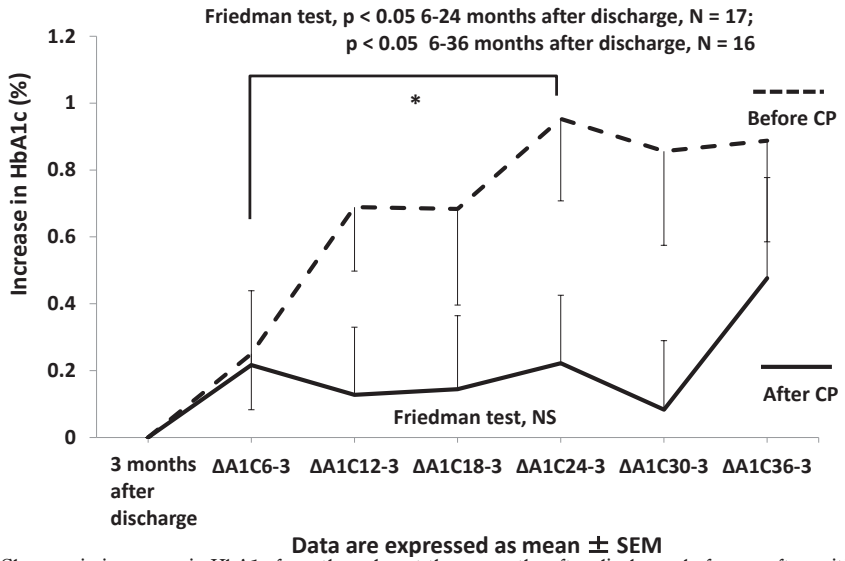

Fig. 1. Changes in increases in HbA1c from the value at three months after discharge before or after critical pathway introduction.
ΔA1C6-3, ΔA1C12-3, ΔA1C18-3, ΔA1C24-3, ΔA1C30-3 and ΔA1C36-3 indicate increase in HbA1c (%) from the value at three months after discharge at 6, 12, 18, 24, 30 and 36 months after discharge, respectively. CP, critical pathway. *, P<0.05 compared with ΔA1C6-3 by Dunn's procedure after Friedman test revealed statistically significant result.

maintained stable glycemic control levels during the observed period.

3. Factors related to worsening of glycemic control at 12, 18 and 36 months after discharge "univariate analyses"

To determine the factors related to worsening of glyce-

mic control, we have defined patients who had a 1.0% or more increase in HbA1c at each time point compared to the value at three months after discharge, as worsening group. There were no significant factors that related to worsening of glycemic control at 12 or 36 months after discharge. At 18 months after discharge, the rate of newly initiated insulin therapy was significantly lower ($P<0.05$) in the worsening group (36.0%) than in the non-worsening group (72.5%) and that of treatment for hypertension was significantly higher ($P<0.05$) in the worsening group (90.9%) than in the non-worsening group (56.0%). Weight gain one year after discharge (a facilitating factor : worsening group, 3.2±2.9 kg ; non-worsening group, 0.9±3.4 kg) and CP introduction (a protecting factor : worsening group, 27.3% ; non-worsening group, 60.0%) showed tendencies toward a weak relationship with worsening of glycemic control at 18 months after discharge ($P=0.05$ and $P=0.06$, respectively).

4. Factors related to worsening of glycemic control at 12, 18 and 36 months after discharge "multivariate analyses"

To clarify the independent background clinical characteristics that contributed to worsening of glycemic control, multivariate analyses were performed (Table 4). Multivariate linear regression analysis revealed that, at 12 months after discharge, CP introduction was an independent factor in non-worsening of glycemic control. Additionally, multivariate linear regression analysis with the forward step-wise method showed that at 18 months after discharge, body weight gain at one year after discharge and age were independent factors in worsening of glycemic control.

Discussion

In the present study, diabetic patients who received educational hospitalization using CP were able to maintain their HbA1c levels for three years to levels as low as those observed at three months after discharge, where the maximum effect of hospitalization on HbA1c had occurred, whereas the HbA1c levels of patients admitted before the introduction of CP revealed a significant and gradual increase after discharge (Figure1 and Table 3). The background characteristics did not differ between the two groups (Table 2), indicating that the educational hospitalization for diabetes glycemic control with CP should be recognized as more effective one than that without CP. However, our study is neither a randomized controlled study nor a prospective one. Consequently, the results should also be interpreted as those from an exploratory research. Also, we did not include factors of changes in treatment of diabetes or hypertension during the observed period. This point is another shortcoming of our present study since not only anti-diabetic agents but also, for example, renin-angiotensin system inhibitors would affect glycemic control levels.

Although there are many reports of the preferable effects of educational hospitalization using CP on glycemic control[4-9], reports on the effects of CP introduction to diabetes educational hospitalization with a follow-up period of more than one year are limited. Nagata *et al.*[11] reported the effect of a 2-week educational program with CP on long-term glycemic control in 126 diabetic patients over a three year period. In their report, however, the effects of the program with and without CP were not examined. Therefore, our present finding that diabetes educational hospitalization with CP is more effective than that without CP for stabilizing glycemic control for three years after discharge seems valuable.

We examined the factors related to worsening of glycemic control after discharge, including all patients together in univariate and multivariate analyses. In relation to worsening of glycemic control during the follow-up period, CP introduction was a weak protective factor at 18 months after discharge in univariate analysis and a significant factor 12 months after discharge in multivariate analysis. In the afore-mentioned report that compared the HbA1c levels for one year after discharge in individuals who receive diabetes educational hospitalization with or without CP, the group with CP had a stable glycemic control level one year after discharge whereas the group without CP exhibited worsening of the HbA1c level one year after discharge, despite having a stable HbA1c level six months after discharge[4]. Thus, CP may maintain a stable glycemic control level 12 or 18 months after discharge. However, there were no relationships be-

tween CP introduction and worsening of glycemic control at 36 months after discharge in our present results from univariate or multivariate analyses. Although the reasons are not clear, several other factors may have affected patients' glycemic control level three years after discharge.

Our present results from multivariate analysis indicate that body weight gain one year after discharge was a significant factor in worsening of glycemic control 18 months after discharge. This result is consistent with that of previous reports[9, 11]. Patients who cannot adhere to diet therapy are naturally at high risk for worsening of glycemic control, even after educational hospitalization.

Furthermore, our present results indicated that there were various other factors related to worsening of glycemic control after discharge from diabetes educational hospitalization. The rate of the newly initiated insulin therapy was significantly lower in the worsening group than in the non-worsening group 18 months after discharge. Reasons for this result are not clear. In our patients who initiated insulin therapy, self-monitoring of blood glucose (SMBG) was also introduced in all patients. SMBG might play a role in maintaining a stable glycemic control level. In multivariate analysis, age was an independent glycemic control worsening factor 18 months after discharge. Therapy for diabetes is complicated since it requires not only taking pills and/or injecting insulin but also adherence to a diet or exercise regimen, regardless of age. For elderly individuals, it may be very difficult to adhere to these complex requirements of diabetes therapy.

The CP was introduced in the chemical and oil industry in the early 1980s as an approach for project management in work with intricate requirements and time schedules. The reasons for utilizing CP in medical care include improvement of the quality of care that can be obtained by a standardized definition of optimal medical care (efficient medical care and nursing), reduction of medical uncertainty, dissemination of economic health and wide-ranging patients' satisfaction[12-18]. In addition, other reasons for utilizing CP are to obtain the understanding and cooperation for medical care from patients and to disclose medical information effectively. Furthermore, for medical doctors, nurses and other medical staffs, it is important that the varied instructions be unified in order to improve communication among all the staffs. In the present study, the benefits of CP utilization, with respect to improvement in patients' satisfaction and of communication of medical staffs had not been examined. To our knowledge, few reports have assessed the effects of CP on these factors in the area of diabetes treatment[4-9]. Thus, a statistically precise randomized controlled study that includes these aspects is warranted in future research.

In conclusions, diabetes educational hospitalization with CP is effective for maintaining a stable glycemic control level after discharge for long-term although the various individual factors have effects on glycemic control levels.

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