

ADHERENCE TO A DIABETIC CARE PLAN PROVIDES BETTER GLYCEMIC CONTROL IN AMBULATORY PATIENTS WITH TYPE 2 DIABETES

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Tight control of blood sugar improves the outcomes for diabetic patients, but it can only be achieved by adhering to a well-organized care plan. To evaluate the effect of a diabetes care plan with reinforcement of glycemic control in diabetic patients, 98 ambulatory patients with type 2 diabetes who visited our diabetes clinic every 3–4 months and who completed four education courses given by certified diabetes educators within 3 months after the first visit, were defined as the Intervention group. A total of 82 patients fulfilling the inclusion criteria for the Intervention group but who missed at least half of the diabetes education sessions were selected as controls. Both groups had comparable mean hemoglobin A1c (HbA1c) levels at baseline, which decreased significantly at 3 months and were maintained at approximately constant levels at intervals for up to 1 year. The HbA1c decrement in the Intervention group was significantly greater than that in the Control group over the 1-year follow-up period (HbA1c change: $-2.5 \pm 1.8\%$ vs. $-1.1 \pm 1.7\%$, $p < 0.01$). The maximal HbA1c decrement occurred during the first 3 months, and accounted for 95.6% and 94.6% of the total HbA1c decrements in the Intervention and Control groups, respectively. In the multiple regression model, after adjustment for age, body mass index, and duration of diabetes, the Intervention group may still have a 12.6% improvement in HbA1c from their original value to the end of 1 year treatment compared with the Control group ($p < 0.05$). Diabetes care, with reinforcement from certified diabetes educators, significantly improved and maintained the effects on glycemic control in ambulatory patients with type 2 diabetes.

Key Words: diabetes, diabetes care, glycemic control
(*Kaohsiung J Med Sci* 2009;25:184–92)

Despite the availability of a variety of therapeutic regimens for the treatment of patients with diabetes mellitus, glycemic control is still fundamental in diabetes management. Better glycemic control decreases

the risk for the development of acute and chronic diabetic complications, and optimizes quality of life [1–3]. The patients' behavioral changes and adherence to a glycemic control program are associated with their self-recognition of the disease state and their knowledge of diabetes, which can be enhanced by the implementation of a diabetes education plan [4–8]. In fact, patient education delivered by certified diabetes educators (CDEs) has become an important part of the diabetes treatment program in medical settings [9,10]. Nevertheless, the delivery of integrated care



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by diabetes specialists, nurses and dietitians, with reinforcement of drug adherence, self-glucose monitoring and dietary control, also significantly contributes to the management of diabetic patients and should not be neglected [11–15].

To clarify whether an integrated care plan, including diabetes education, does have benefits in terms of the outcomes of glycemic control, however, remains a challenge because of the coexistence of many other factors, e.g. the demographic and physiological characteristics of patients, teaching methods used, types of antidiabetic medication, and the presence of complications. Randomized control trials (RCTs) designed by specialists from multiple disciplines and that incorporate the dedication of patients, healthcare providers and institution facilities are highly recommended as the most reliable study design to address this issue [16]. However, meta-analysis of the results of several RCTs revealed that patient education exerted only a modest effect on the glycemic control of diabetic patients [17–19]. Furthermore, the effect of an education plan on glycemic control reportedly declined over the diabetes disease course [18], unless self-management was enhanced by reinforcement of the education plan [20].

Thus, although diabetes education has an important role in managing diabetic patients, the importance of diabetes education has been overemphasized. However, the patient adherence to the care plan is often overlooked. The purpose of the present study was to determine whether adherence to a new diabetes care plan implemented at a regional hospital was effective in enhancing the glycemic control of ambulatory patients with type 2 diabetes.

MATERIALS AND METHODS

This study was conducted at a 464-bed regional hospital of Kaohsiung City in southern Taiwan between January 2000 and June 2001. Ambulatory patients with diabetes were put under the care of a diabetes team, which was composed of diabetes specialists, nurses and dietitians of CDEs. We recruited 98 ambulatory patients with diabetes as the Intervention group according to the following inclusion criteria: (1) patients with type 2 diabetes who were diagnosed and treated by diabetes specialists at the diabetes clinic at our hospital; (2) patients with clear consciousness,

capable of verbal comprehension and communication, and independent in terms of self care; and (3) patients able to return for regular follow-up at the diabetes clinic every 3–4 months and take four diabetes education courses within 3 months after their initial visit. To study the effectiveness of diabetes education on glycemic control, another 82 diabetic patients, who were regularly treated at out-patient clinics, were selected retrospectively by chart review, and fulfilled the inclusion criteria described above, except that they had taken only one or two diabetes education courses over 3 months, were included as the Control group.

The introduction of diabetes mellitus and diabetes-related complications, exercise, antidiabetic medication, dietary principles for control of blood glucose, and social and psychological support, for example, were all included in the education course. Two nurses, who were qualified CDEs, were responsible for the implementation of this education program. The patients referred to the CDEs from the diabetes specialists were first evaluated by the CDEs, and then received a 30–45-minute one-to-one instruction from the CDEs according to the disease status and needs of the patient. The CDEs then arranged subsequent interviews in which education courses would be given four times within 3 months after the first visit. In addition, the patients were able to ask the CDEs questions regarding their experiences and to obtain answers in the subsequent follow-up periods until the end of study. In terms of diabetes treatment, most of the patients took oral hypoglycemic agents for blood glucose control, and insulin was used by only two patients. Basic demographic and physical characteristics of the patients, presence of complications and laboratory tests were investigated and collected at baseline and every 3–4 months for 1 year. Blood hemoglobin A1c (HbA1c) was measured with an immunoassay, using a monoclonal antibody against the conjugated site of glucose and six amino acids on the N-terminal of hemoglobin β chain. The extent of the reaction was determined using an automatic chemistry analyzer (COBAS INTEGRA 700; Roche Diagnostics, Indianapolis, IN, USA).

Data processing, statistical analyses and graph drawing were conducted using SPSS 11.0 (SPSS Inc., Chicago, IL, USA) and Prism 4.0 (GraphPad Software Inc., San Diego, CA, USA). For the descriptive statistics for demographic and other characteristics of patients

in different groups, the continuous variables are expressed as mean \pm standard deviation, and categorical variables are expressed as frequencies or percentages. One-way repeated-measures analysis of variance was used to determine the differences in HbA1c levels within each group and between groups at various time points. Values were compared between groups using Student's *t* test. Multiple regression analyses were carried out to determine the effects of age, sex, body mass index (BMI), duration of diabetes, group, and duration of diabetes \times group on the magnitude of HbA1c improvement. The magnitude of HbA1c improvement was defined as the difference between the HbA1c level at a particular time point and the baseline level to the baseline level, and is expressed as a

percentage. A *p* value less than 0.05 was considered to be statistically significant.

RESULTS

The patient characteristics and the levels of HbA1c are shown in the Table. There were no significant differences between the Intervention and Control groups in terms of age, sex ratio, marital status, educational level, family history of diabetes, body height, body weight, BMI, smoking, and frequency of follow up. Although the Control group had a longer duration of diabetes (8.8 ± 6.7 vs. 5.3 ± 5.7 years, $p < 0.05$), the HbA1c levels at baseline were not significantly

Table. Characteristics of the Intervention and Control groups*†

	Intervention group (<i>n</i> = 98)	Control group (<i>n</i> = 82)
Age (yr)	57.5 \pm 11.3	58.9 \pm 11.0
Male	46.0	51.8
Married	98.0	100
Family history of diabetes	48.0	53.0
Body height (cm)	160.0 \pm 7.7	159.6 \pm 7.5
Body weight (kg)	65.0 \pm 10.3	66.2 \pm 11.4
Body mass index (kg/m ²)	25.2 \pm 3.3	25.8 \pm 3.4
Education level		
Below primary school	32.0	44.6
Primary and junior school	38.0	22.9
Above junior school	30.0	32.5
Smoking	24.0	21.7
Outpatient clinic visits		
> 12 times	64.0	53.0
9–12 times	25.0	26.5
< 9 times	11.0	20.5
Duration of diabetes (yr)‡	5.3 \pm 5.7	8.8 \pm 6.7
Diabetes-related complications		
Neuropathy	35.0	38.6
Cardiovascular diseases‡	6.0	15.7
Retinopathy	33.0	44.6
Nephropathy‡	14.0	31.3
Laboratory data		
Hemoglobin A1c at baseline (%)	9.4 \pm 1.8	9.2 \pm 1.5

*Data presented as mean \pm standard deviation or %; †statistical comparisons using Student's *t* test or χ^2 test; ‡significant differences between the Intervention and Control groups ($p < 0.05$).

different between groups (Control group vs. Intervention group: $9.2 \pm 1.5\%$ vs. $9.4 \pm 1.8\%$, $p > 0.05$), and there was no correlation between the duration of diabetes and the baseline HbA1c levels ($r = -0.045$, $p > 0.05$; Pearson's correlation). The percentage of patients with complications, including cardiovascular diseases or nephropathy, was higher in the Control group. However, the HbA1c levels in patients with or without each complication were not different.

Despite the comparable HbA1c levels at baseline in the two groups (Table), the HbA1c levels at 3 months, 6 months, 9 months and 12 months were lower in the Intervention group than in the Control group (Figure 1). The repeated-measures analysis of variance revealed that the differences in HbA1c levels at these

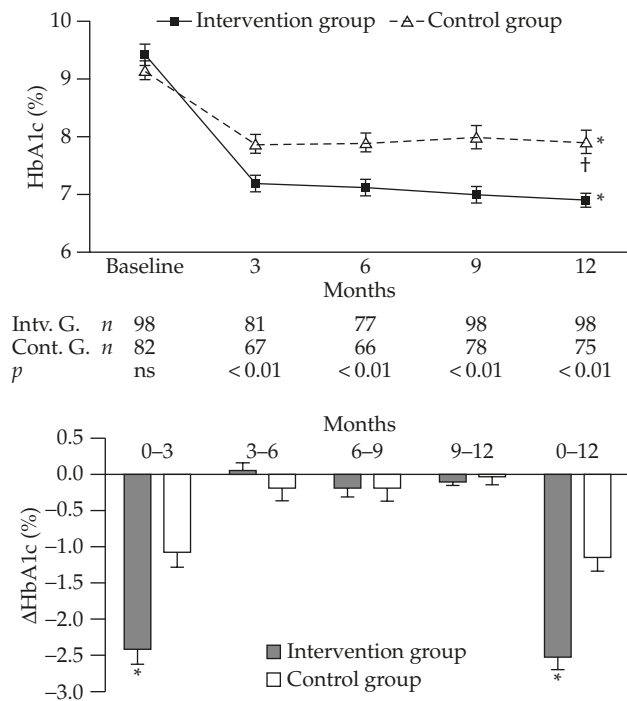


Figure 1. (A) Hemoglobin A1c (HbA1c) levels (mean \pm standard error of the mean) in the Intervention group ($n = 98$) and Control group ($n = 82$) at baseline and at time intervals of 3 months. Significant differences are noted in the improvement of HbA1c within each group ($*p < 0.05$) and between groups ($^{\dagger}p < 0.05$) by repeated-measures analysis of variance. The differences between the two groups are demonstrated to be significant at all time points, except for at baseline, by Student's t test ($p < 0.01$). (B) The magnitude of HbA1c decrement at different intervals during the 1-year study period in the Intervention group and Control group. Statistically significant differences can be seen between groups at 3 months and for the total decrement (Student's unpaired t test; $*p < 0.01$). The HbA1c decrements are greatest at 3 months, and were responsible for 95.6% and 94.6% of the total HbA1c decrements in the Intervention and Control groups, respectively.

time points within each group and between both groups were statistically significant. The HbA1c level in the Intervention group was significantly lower than that in the Control group at 12 months (HbA1c: $6.9 \pm 1.2\%$ vs. $7.9 \pm 1.8\%$, $p < 0.01$; Figure 1A), and the HbA1c decrement at 12 months in the Intervention group was significantly greater than that in the Control group (Δ HbA1c: $-2.5 \pm 1.8\%$ vs. $-1.1 \pm 1.7\%$, $p < 0.01$; decrement: 26.7% vs. 12.5%; Figure 1B). The maximal HbA1c decrement occurred during the first 3 months, and accounted for 95.6% and 94.6% of the total HbA1c decrements in the Intervention and Control groups, respectively (Figure 1B).

Figure 2 shows the change in percentage in each HbA1c category. In both groups, the percentages shifted toward lower HbA1c categories at 3 months, and the effect persisted for the duration of the study. However, such a shift indicative of improved glycemic control was more pronounced in the Intervention group. To determine whether the decrement in HbA1c was more pronounced during the first 3 months, the differences in HbA1c between 3 months and baseline were plotted against the baseline values in both groups (Figure 3). This showed that higher absolute values of HbA1c at baseline were associated with greater HbA1c decrements at 3 months. This phenomenon was more pronounced in the Intervention group than in the Control group, as shown in Figure 3.

To identify the factors associated with the improvement in HbA1c during the study period, a multiple regression model with independent variables was tested. The parameters associated with the magnitude of HbA1c improvement can be represented in a regression equation:

$$\begin{aligned} \text{Magnitude of HbA1c improvement} = & -28.435 \\ & + (12.556 \times \text{Intervention group}) + (0.954 \times \text{BMI}) \\ & + (0.336 \times \text{age}) - (0.504 \times \text{diabetes duration}) \end{aligned}$$

This equation revealed that the Intervention group may have a 12.6% improvement in HbA1c from the original value to that at 1 year compared with the Control group ($p < 0.05$). However, the effect on the improvement of HbA1c was only 0.34% for age, 0.95% for BMI, and decreased by 0.50% for diabetes duration (all $p < 0.05$). This model had an R^2 of 0.198 and an adjusted R^2 of 0.179, which means that about 19.8% of the variation in the improvement of HbA1c could be explained by this model.

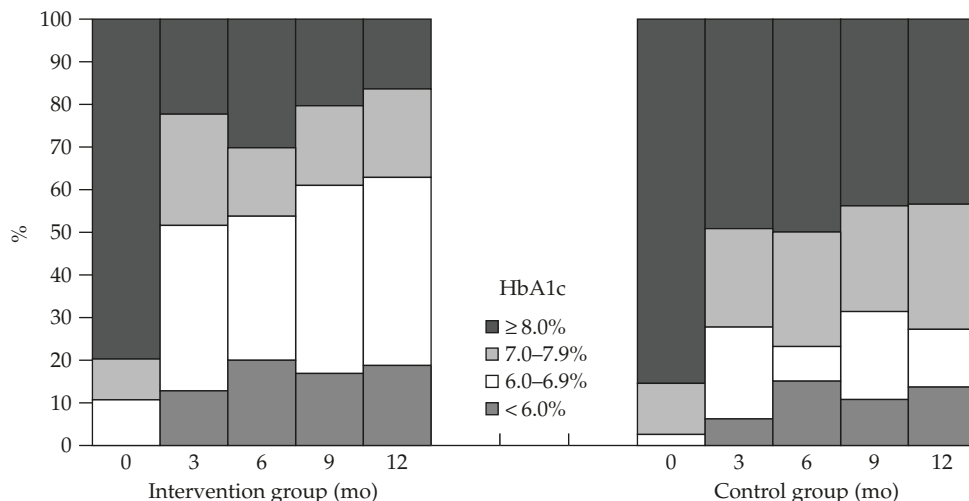


Figure 2. The percentage of patients in each hemoglobin A1c (HbA1c) category at different time intervals during the 1-year study period in the: (A) Intervention group (n=98); and (B) Control group (n=82). A greater proportion of patients shift towards the lower HbA1c categories at 3 months compared with at baseline, and persist up to 1 year. This shift in HbA1c levels is more pronounced in the Intervention group.

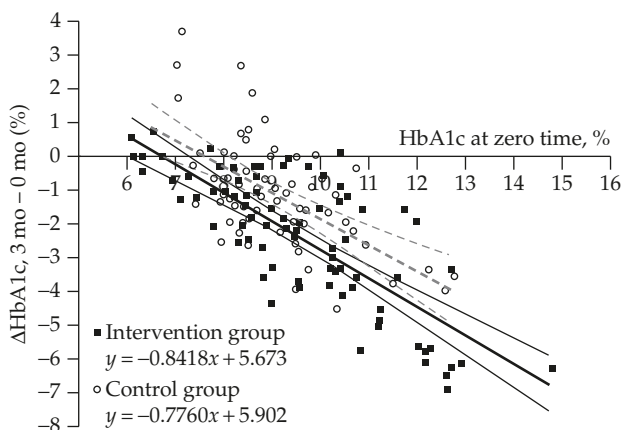


Figure 3. Correlation between hemoglobin A1c (HbA1c) level at baseline and HbA1c decrement at 3 months in the Intervention (n=81) and Control (n=67) groups. This shows that absolute values for HbA1c at baseline were associated with greater decrements in HbA1c at 3 months. This phenomenon, as shown by regression lines, was more pronounced in the Intervention group (solid lines) than in the Control group (dash lines).

DISCUSSION

Although there is some discrepancy in the results, several studies have revealed the beneficial effect of integrated care and diabetes education on glycemic control [4,5,21], based on whether a patient education program becomes an integral part of diabetes management. In the present study, the HbA1c level of patients who received a recently introduced diabetes education plan decreased from $9.4 \pm 1.8\%$ at baseline

to $6.9 \pm 1.2\%$ at 12 months, corresponding to a decrement of 26.7%, compared with a 12.5% decrement in the Control group. The significant difference in HbA1c change between the two groups demonstrates the beneficial effect of the care plan. This finding was further confirmed by the results of multiple regression analysis, in which the group factor accounted for a 12.6% reduction in the HbA1c level in the Intervention group.

RCTs are considered the most reliable study design to address the effect of diabetes education on glycemic control [16]. Meanwhile, meta-analysis of the results of several RCTs has been well addressed [17–19]. However, we were confined to a case-control study because of the complexity in conducting an RCT in this setting. This study was originally part of a pilot study of a nation-wide program of diabetes education and clinical pathways. It was not designed as an RCT, and the main objective was to establish better care of patients with diabetes through integrated care, including the education plan. Nevertheless, this care plan with its emphasis on diabetes education and professional management led to positive outcomes in terms of glycemic control.

In addition to the reports describing the varied levels of success achieved by programs in promoting glycemic control [17–19], Jiang et al [22] reported that a diabetes education program improved the short-term glycemic control in Taiwanese patients, and determined that the intensity of diabetes education

was the only significant variable associated with the decrease in fasting blood glucose. Keers et al [23] showed that their Multidisciplinary Intensive Education Programme improved glycemic control and quality of life in diabetes patients with prolonged self-management difficulties. Recently, Tien et al [24] demonstrated the effectiveness of a comprehensive diabetes care program in lowering the HbA1c levels. They found that male patients with a shorter duration of diabetes history and higher baseline levels of HbA1c were more likely to achieve better glycemic control [24]. However, the magnitude of the HbA1c decrement of up to 26.7% in the present study is higher than that achieved in these three reports. In Jiang et al's study, the HbA1c decrement was 3.2% and 7.4% in patients receiving basic and advanced education programs, respectively, after 4 months of care [22]. Meanwhile, in Keers et al's study, the HbA1c decrement was 5.1% at 3 months after the Multidisciplinary Intensive Education Programme [23]. Finally, in Tien et al's study, the HbA1c decrement was only 2.6% at 3 months [24]. Differences in patient selection and patient characteristics might be responsible for these differences.

In this study, we found that patients with higher baseline HbA1c had larger HbA1c decrements, which was also observed in another study [23]. Our patients were not restricted to those with relatively high HbA1c levels, as shown in Figure 3, and only 19.6% of patients in the Intervention group and 14.6% in the Control group had an HbA1c level less than 8.0%. This means that our patients had relative high glycemic status, which might explain why the magnitude in HbA1c improvement was greater in our study. Furthermore, a large proportion of our patients were newly diagnosed, newly referred and new receivers of diabetes education (94%), meaning that they might display better compliance compared with later stage diabetic patients. Newly diagnosed patients with diabetes have been shown to display better responses to medication and the education plan from different aspects, and thus generally have better glycemic control [25]. This might, at least partially, be because they have more interest and motive for complying with medication and dietary control in their daily living.

In addition, the majority of the HbA1c decrement was achieved during the first 3 months of the integrated care plan, which contributed 95.6% of the total HbA1c decrement over the year. This means that the

effect of diabetes care on the improvement of glycemic control was most pronounced during the initial phase of the intervention program, during which the diabetes education was delivered. This result is consistent with that in other studies [26,27]. Some studies have demonstrated that a more intensive education and care program might be required to achieve further reduction in HbA1c levels [20]. Nevertheless, maintaining the beneficial effect of diabetes education on glycemic control is already a real challenge [28]. A gradual deterioration in glycemic control has been observed with prolongation of diabetes [8], which can be attributed to factors such as increased insulin resistance or decreased insulin secretion, lack of response to antidiabetic medication, loss of patient compliance, or fatigue on the part of the care facility. Therefore, the absence of further improvements in glycemic control in the subsequent 9 months might not reflect the ineffectiveness of the integrated care plan during that period of time but rather its remarkable work in maintaining the effect on glycemic control in consideration of persistent significant differences in absolute HbA1c levels between the Intervention and Control groups.

Limitations in the study design and interpretation of the results should be carefully considered. Because this was a retrospective study, selection bias in terms of the study population could exist, although this was minimized as much as possible. The Control group had relatively longer duration of diabetes, and more diabetic complications. These might hinder the improvements in glycemic control [29], although neither had an effect on the differences in HbA1c levels between the groups in this study. Nevertheless, the control patients were regularly followed-up. They received treatment and their HbA1c was measured in the same manner as the Intervention group; the only difference was that the subjects in the Control group participated in none, one or two diabetes education sessions. The reasons for subject non-participation in the courses were diverse. Some were followed-up at night clinics, and others were unable to attend because of personal or family reasons. By the very fact of attending follow-up regularly, these subjects in the Control group could be regarded as a group of patients who have better compliance with medication and dietary control compared with those who miss their follow-up consultations. This might explain why there was some improvement in their HbA1c levels

during the study, albeit less than that in the Intervention group [20].

The present study revealed that ambulatory patients with type 2 diabetes who received an integrated care plan, delivered by diabetes specialists and CDEs, had better glycemic control over a 1-year follow-up period. This effect was most pronounced during the first 3 months; this period saw the majority of the HbA1c decrement. Whether patients received a diabetes care plan or not was the major determinant for the improvement in glycemic control. Therefore, a diabetes care plan implemented with a reinforcement approach can provide better short-term improvements and maintenance of glycemic control in ambulatory patients with type 2 diabetes.

ACKNOWLEDGMENTS

The authors would like to express their appreciation to Yi-Hsin Yang, PhD, Associate Professor of the Graduate Institute of Oral Health Science, College of Oral Medicine, Kaohsiung Medical University, for statistical advice.

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第二型糖尿病病患遵從糖尿病照護計畫者 血糖控制較佳

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糖尿病患者嚴格的血糖控制可獲得較佳的預後，但必須有好的照護計畫。為評估糖尿病照護與加強血糖控制計畫之成效，本研究收錄 98 名第二型糖尿病病患為介入組，病患每三至四月門診一次，並於初次門診後的三個月內由經過認證之糖尿病衛教師教育完成四次糖尿病衛教內容。另有 82 名相似條件的糖尿病病患但未完成四次衛教者作為控制組。兩組基礎期的糖化血色素質相近，而在第三個月時兩組各即呈有意義地下降，而後一直平穩而持續地維持此一水準。一年多的追蹤期中，糖化血色素的降幅在介入組明顯地大於控制組 (ΔHbA1c : $-2.52 \pm 1.84\%$ vs. $-1.14 \pm 1.73\%$ 、 $p < 0.01$)。糖化血色素的最大降幅發生於前三個月且各佔介入組與控制組整體降幅之 95.6% 與 94.6%。控制年齡、性別、質量數、與糖尿病罹病期後之多重回歸模式顯示，在經一年多的治療後糖化血色素的降幅在介入組較控制組大 12.6% ($p < 0.05$)。我們結論由經過認證之糖尿病衛教師參與之糖尿病照護與加強血糖控制計畫可有意義地改善與維持第二型糖尿病病患之血糖控制。

關鍵詞：糖尿病，糖尿病照護，血糖控制

(高雄醫誌 2009;25:184-92)

收文日期：97 年 11 月 14 日

接受刊載：98 年 4 月 13 日

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