Creation of Drug Compliance Instruction Program for Patients with Type 2 Diabetes and Evaluation of its Effectiveness

Koichiro Atsuda*1,2, Soichi Shibata1, Mitsuru Machida1,2 and Kazuo Yago2,3
Department of Pharmacy, The Kitasato Institute Hospital1
Center for Clinical Pharmacy and Clinical Sciences Division of Hospital Pharmacy, School of Pharmaceutical Sciences, Kitasato University2
Department of Pharmacy, Kitasato University Hospital3

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The aim of this study was to devise a Drug Compliance Instruction Program (DCIP) for patients with type 2 diabetes taking oral hypoglycemic agents (OHA) and to assess its effectiveness. The new program was devised to improve levels of understanding and implementation in drug therapy for diabetes with the aims of contributing to and evaluating the effectiveness of such therapy. As its major features, the program uses the level of drug therapy implementation as an indicator of drug compliance and gives patients instructions on several occasions to ensure that they continue to be effective. Subjects were 109 type 2 diabetes outpatients who had HbA1c levels of 7% or more and were taking OHA. To study the effectiveness of the instructions, patients were randomly assigned to two groups: a single instruction group (n = 66), and a multiple instruction group (n = 43), whose subjects received instructions at least twice.

DCIP significantly improved the levels of understanding (p = 0.001) and implementation (p = 0.033) of the drug therapy. The status of glycemic control based on HbA1c levels was used as an indicator in the evaluation of instructions, whose educational effect was significantly higher in the multiple instruction group than in the single instruction group (p = 0.042). By enhancing levels of understanding and implementation in drug therapy for diabetes, DCIP significantly improved glycemic control, and this was maintained when instructions were given on several occasions.

Key words — type 2 diabetes, compliance, oral hypoglycemic agents, glycemic control, patient care, instruction program

Introduction

Outpatients with Type 2 diabetes who had been receiving drug therapy received personal instruction. As a result, it was discovered that levels of understanding in patients taking oral hypoglycemic agents (OHA) was low in comparison to those patients on insulin. Consequently, we devised an early stage Drug Compliance Instruction Program (DCIP) for OHA patients, and this program contributed to glycemic control values improving two to four months after instruction.1,2

When implementing the early stage program, attention was focused on the low level of drug compliance. To raise levels of drug compliance, it was necessary to be able to achieve the desired effect of the drug therapy.3,4 However, in this study it was found that compliance did not necessarily mean satisfactory results. The reason for this was that patients did not fully understand the significance of the drug therapy and were worried about the side effects of the medication. Furthermore, it was discovered that the area where the primary stage program needed to be improved was in the duration of instructional effectiveness, in that it was only effective for a short period of time. With regards to maintaining this effect, it had been reported that a single instructional session was only effective for a period of about three months, suggesting that multiple instructional sessions were necessary.5

Thus, with the aim of making a contribution to the treatment of diabetes, we devised a new DCIP primarily focusing on raising levels of understanding and implementation of drug therapy and analyzing its efficacy. In this program, the level of implementation was taken as an indicator of compliance. A further aim was to investigate the continuity of the effectiveness of instruction, thus the subjects were divided into two groups, the single instruction group and the multiple instruction group, and the results were compared.

1 港区白金5-9-1; 5-9-1, Sirokane, Minato-ku, Tokyo, 108-8642 Japan
2 港区白金5-9-1; 5-9-1, Sirokane, Minato-ku, Tokyo, 108-8641 Japan
3 神奈川県相模原市北里1-15-1; 1-15-1, Kitasato, Sagamihara-shi, Kanagawa, 228-8555 Japan
2. Evaluation of Instructional Effectiveness

Methods

Subjects consisted of 109 type 2 diabetes outpatients with HbA1c levels of at least 7% while taking OHA. All subjects took part in the DCIP and were randomly assigned at initial session to either the single (first time only) instruction group (n = 66) or the multiple (more than one) instruction group (n = 43). All subjects received adequate information regarding both the aim and contents of the study and took part once informed consent had been given.

1. Outline of the Drug Compliance Instruction Program

For those patients who met the selection criteria for this program, levels of understanding and implementation of drug therapy were assessed. The level of understanding was assessed using five items: 1) the characteristics of the drug therapy, 2) the name of the medication prescribed, 3) the action of the medication, 4) what to do when hypoglycemia occurs, and 5) what to do on sick days, where one point was given for a correct answer with a maximum score of five points. Implementation was assessed by evaluating drug compliance, in other words, how often the subjects failed to take their medication. On a scale of 1–3, forgetting to take medication two times or less per week was given a score of 3, three to five times earned a score of 2, and at least six times meant a score of 1. Instructions regarding the medication took place after the previously mentioned assessment had taken place. Instruction concentrated on raising compliance, focusing on an explanation of the importance of taking the medication, and erasing concerns about side effects.

In the multiple instruction group, the second instructional session was given during the medical re-examination, about two to four weeks after the initial instruction. Instructions similar to the initial instruction were given after levels of understanding and implementation of drug therapy had been reassessed. On average, subjects received instruction 2.6 times on a one-to-one basis in a guidance room by three pharmacists who were specialists and had a knowledge of the equal level in the field of diabetes. The average time required for the instruction was 20 minutes for the initial session and 10 minutes for subsequent sessions. The contents of these sessions were recorded on a report sheet and used by the attending physician for feedback. While this system was a DCIP for outpatients with type 2 diabetes taking OHA within the hospital, doctors, nurses, and dieticians, each of whom has their role, worked closely with each other to treat and guide the patients.

2. Evaluation of Instructional Effectiveness

1) Evaluation of Instructional Effectiveness

With regards to evaluating the instructional effectiveness and using the levels of understanding and implementation of drug therapy as an indicator, a comparison was made between the values obtained after the first and second sessions in the multiple instruction group (n = 43).

2) Evaluation of Effectiveness of Multiple Instruction

Evaluation of instructional effectiveness was based on the 51 subjects in the single instruction group and the 35 subjects in the multiple instruction group who had no changes in OHA prescriptions, that is to say, no increase in dosage, no additional medication, and no progression to insulin four months after receiving instruction. Changes in the state of glycemic control based on HbA1c levels two, four, and six months after instruction were taken as indicators in the evaluation. This research was conducted between May 1997 and July 1998.

A statistical analysis was carried out using the Wilcoxon Test and the Bonferroni/Dunn Test, and the software used in the analysis was Stat-View Ver.5.0 (SAS Institute Inc.). All data was expressed as mean±SD and a risk ratio of less than 5% was considered to be statistically significant.

Results

1. Evaluation of Instructional Effectiveness

With regards to levels of understanding of the drug therapy, the rate of correct answers increased for each item after instruction, and a comparison of the total score rose significantly after instruction when compared to the initial instructional session and the second instructional session (2.8±0.9 points, 4.1±1.1 points, respectively, p = 0.001). When each item was taken separately, the percentage of correct answers for the name of the medication, its action, and what to do on a sick day doubled. Implementation of the drug therapy (drug compliance) also improved significantly from the first instructional session to the others with values of 2.5±0.7 points and 2.7±0.5 points, respectively, p = 0.033 (Table 1).

2. Evaluation of Effectiveness of Multiple Instruction

1) Information on Patients

Information on patients in both groups who were subjects in the evaluation of effectiveness of multiple instruction at the time of the first instructional session is provided in Table 2. While a significant difference was not found in age, duration of diabetes, duration of drug therapy, HbA1c values, levels of understanding, compliance with drug therapy, and medication, a significant difference was found between the groups for body mass index (BMI) (p = 0.01). For the amount of medication prescribed, the difference between the groups was not significant.

2) Changes in the State of Glycemic Control

While HbA1c values in the single instruction group showed a tendency toward improvement before instruction and two and four months after (8.55±1.44%→8.19±1.35→8.26±1.56), measures obtained six months post instruction resulted in values comparatively worse (8.96±1.58) than those before the initial instruction. On the other hand, in the multiple instruction group improvement was seen after the two-, four-, and six-month periods of instruction when compared to the initial instruction (8.33±0.98%→8.05±1.27→7.90±1.08→7.92±1.19). Using the Bonferroni/Dunn Test, the educational effect was significantly higher in the multiple instruction group compared with the single in-
struction group \((p = 0.042)\); in addition, a significant improvement was seen four months after the initial instruction \((p = 0.047)\). (Fig. 1)

**Discussion**

It cannot be stressed enough that drug compliance in order to obtain the therapeutic effect of drug therapy is critical\(^3,4\). It has been reported that less than half of patients on oral hypoglycemic agents (OHA) were fully compliant with instructions for taking their medication\(^1\). Such a situation is unacceptable in the treatment of diabetes, and it is desirable that pharmacists take part in providing instruction to patients with diabetes regarding their drug therapy.

Previously when an investigation was conducted at the present institution into reasons for the decline in drug compliance, it became clear that not only did few patients understand the significance of their drug therapy but also that
many patients lived in fear of the side-effects or adverse drug interactions. Furthermore, more patients than previously imagined stopped taking their medication without informing their doctor. This suggests that distribution of correct information on the drugs and instruction on the importance of taking those drugs is necessary for patients being treated with OHA.

The primary aim of this study was to improve not only the level of understanding but also the level of compliance with drug therapy, ultimately resulting in a program that contributes to the treatment of diabetes. To achieve this, it was important that DCIP explained the importance of drug therapy and alleviated the concerns about any side effects. The most fearful side effect was hypoglycemia for patients on OHA. So, in order to relieve concerns about the side effects, we provided detailed instructions about the symptoms of hypoglycemia and what to do when it occurs. By doing this, a significant improvement was observed in both the understanding and level of compliance with drug therapy when data were compared before and two to three months after instruction. Furthermore, a significant improvement was also shown in HbA1c. The results of this study indicated that the program was effective and the aims of the study fulfilled.

A secondary aim was to investigate the continuity of the instructional effectiveness. To do this, a comparative study was conducted on the single and multiple instruction groups focusing on HbA1c when compared to pre-instruction values, measures of HbA1c levels worsened in the single instruction group six months after instruction, revealing a limit to the effectiveness of instruction. However, in the multiple instruction group, values continued to improve even six months after the initial instruction. Statistically, the educational effect was significantly higher in the multiple instruction group compared with the single instruction group. This suggested that multiple instructional sessions were necessary.

The results suggest that when focusing on improved drug compliance for patients taking OHA, a single instructional session is insufficient. During follow-up with patients, multiple instructional sessions are vital.

Pharmacists may play a major role in preventing secondary failure of OHA, progression to insulin, and in preventing complications by concentrating on explaining the importance of taking medication while giving instruction on general drug compliance to patients who develop no serious complications from OHA. Just how significant a role pharmacists assume in the treatment of diabetes and its efficacy became clear in this study.

In conclusion, the Drug Compliance Instruction Program significantly improved glycemic control by improving levels of understanding and compliance with drug therapy. The effectiveness was maintained when multiple instructional sessions were conducted, and the role of the pharmacist in the treatment of diabetes and its efficacy was significant.

References


