Insulin adjustment by a diabetes nurse educator improves glucose control in insulin-requiring diabetic patients: a randomized trial

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Abstract

Background: Diabetic patients taking insulin often have suboptimal glucose control, and standard methods of health care delivery are ineffective in improving such control. This study was undertaken to determine if insulin adjustment according to advice provided by telephone by a diabetes nurse educator could lead to better glucose control, as indicated by level of glycated hemoglobin (HbA_{1c}).

Methods: The authors conducted a prospective randomized trial involving 46 insulin-requiring diabetic patients who had poor glucose control (HbA_{1c} of 0.085 or more). Eligible patients were those already taking insulin and receiving endocrinologist-directed care through a diabetes centre and whose most recent HbA_{1c} level was 0.085 or higher. The patients were randomly assigned to receive standard care or to have regular telephone contact with a diabetes nurse educator for advice about adjustment of insulin therapy.

Results: At baseline there was no statistically significant difference between the 2 groups in terms of HbA_{1c} level (mean [and standard deviation] for standard-care group 0.094 [0.008] and for intervention group 0.096 [0.010]), age, sex, type or duration of diabetes, duration of insulin therapy or complications. After 6 months, the mean HbA_{1c} level in the standard-care group was 0.089 (0.010), which was not significantly different from the mean level at baseline. However, the mean HbA_{1c} level in the intervention group had fallen to 0.078 (0.008), which was significantly lower than both the level at baseline for that group ($p < 0.001$) and the level for the standard-care group at 6 months ($p < 0.01$).

Interpretation: Insulin adjustment according to advice from a diabetes nurse educator is an effective method of improving glucose control in insulin-requiring diabetic patients.

Several studies have shown that good glucose control is associated with a decreased risk of microvascular and macrovascular complications in type 1[1,2] and type 2[3–5] diabetes. However, surveys have revealed that in the community setting most people with diabetes have poor glucose control.[6,7] In most studies of glucose control, patients in the standard-care arm have received traditional diabetes care, which consists of physician visits every 3 months in addition to education through a diabetes centre.[1–3,8] This method of care is ineffective in achieving glucose control, even though it is more intense than what is received by most patients in the community setting.[6,7]

A common approach for the intervention arm of the studies was to provide regular telephone contact with diabetes nurse educators for advice about insulin adjustment.[1–] We have used this method for a number of years in our diabetes-in-pregnancy clinic,[9] and it has been shown to be effective in other models as well.[10] Other studies have shown that nurse educators can provide care superior to that of physicians for a general diabetes population in a primary care setting.[11] Our study was designed to determine whether the addition of regular telephone contact with a diabetes nurse educator would lead to improvements in levels of glycated hemoglobin (HbA_{1c}) in insulin-requiring patients with poor glucose control in the setting of a hospital diabetes clinic.

Evidence

Études

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Methods

We thought that the strongest test of our hypothesis would be achieved by studying patients whose glucose levels were poorly controlled despite standard diabetes care. The null hypothesis was that the addition of regular telephone contact with a diabetes nurse educator for help with insulin adjustment would not improve glucose control, as indicated by HbA_{1c} level.

Sample-size calculations were based on the need to detect a decrease of 1 standard deviation (a difference of 0.010 in our sample HbA_{1c} values) in the intervention arm. For a 2-sided *t* test with $\alpha = 0.05$ and $\beta = 0.9$, we needed 21 patients per arm, a number fairly close to the numbers in the study by Ohkubo and associates.[3] We enrolled 23 patients in each arm to allow for possible drop-outs.

Patients were eligible for the study if they were already receiving insulin, had undergone standard diabetes education, were able to monitor blood glucose levels at home, were being followed through our diabetes centre and were under the care of one of the endocrinologists and if their most recent HbA_{1c} level was 0.085 or greater. Exclusion criteria were inability to communicate regularly by phone, a contraindication to tight glucose control, another serious illness or use of an insulin pump. The charts of patients meeting these criteria were selected at random, and the patients were invited to participate. If a patient refused to participate, his or her chart was replaced and another was selected at random. Once the number of participants needed was obtained, each patient met the study nurse (S.E.K.), signed an informed consent form and was randomly assigned to either the standard-care or the intervention arm. The allocation sequence was generated from a random number table and concealed in sequentially numbered, opaque, sealed envelopes until the assignment of patients to the study arms. The primary endpoint was the mean HbA_{1c} level 6 months after entry into the study. As a secondary outcome we examined the proportion of patients in each group who experienced a 10% reduction in HbA_{1c} levels over the study period. HbA_{1c} measurements were done in clinical laboratories (with high-pressure liquid chromatographic equipment); the normal range was 0.043 to 0.062. The laboratory technicians performing the measurements had no knowledge of the study and were blinded as to the patients' group assignment.

All patients were given free human insulin (Eli Lilly and Co.), syringes, glucose meters and glucose test strips (Advantage, Boehringer-Mannheim Canada, Laval, Que.) for the duration of the study to ensure that the cost of supplies was not a factor in the outcome.

Patients in the standard-care group were given supplies as needed and told to continue their usual contact with the endocrinologist for insulin adjustment. Their physicians were aware of the details of the study and knew which of their patients were enrolled. These patients continued their regular clinic visits, including HbA_{1c} measurement, every 3 months. No extra data were collected for these patients to avoid altering their usual pattern of care.

Patients in the intervention group made arrangements for regular telephone contact with the nurse. The frequency and duration of phone contact was individualized and varied widely among patients, but averaged 3 calls per week, each lasting 15 minutes. The time required tended to decrease over the course of the study. Insulin adjustments were recommended during most calls. The nurse had adjusted insulin therapy for several years in a diabetes-in-pregnancy clinic and did not receive any additional training for this study. She was not on staff at the diabetes clinic where study participants were receiving care and did not know the patients before the study. She followed general guidelines for insulin adjustment but used her judgement for each individual decision. She reviewed each patient's diabetes records with his or her physician as needed, typically about once every 2 weeks.

Statistical analysis consisted of 2-tailed paired *t*-tests (for the HbA_{1c} values) and χ^2 tests.

Ethical approval for the study was obtained from the University of British Columbia Ethics Committee.

Results

Twenty-three patients were assigned to each arm of the study. Table 1 shows that there were no statistically significant differences between the 2 groups at baseline with respect to age, sex, type or duration of diabetes, duration of insulin therapy or complications.

Patients in the intervention and standard-care groups had similar mean HbA_{1c} levels at baseline; the mean HbA_{1c} level (and standard deviation [SD]) in the intervention group was 0.094 (0.008) whereas that in the standard-care group was 0.096 (0.010). Patients in the intervention group experienced a highly significant decline in HbA_{1c} level over the study period, whereas there was no significant change for patients in the standard-care group. Twenty (87%) of the 23 patients in the intervention group experienced a decline in HbA_{1c} of at least 10%, whereas only 8 (35%) of those in the standard-care group did ($p < 0.001$). Seven patients (30%) in the standard-care group experienced an increase in HbA_{1c} level during the study, such that there was no change in the group mean. There was no correlation between the degree of change in HbA_{1c} level and age, sex or type of diabetes. Differences in the HbA_{1c} level between the 2 groups were not affected by regression adjustment for age, sex or type of diabetes.

No patient in the standard-care group experienced development or progression of a diabetes-related complication during the study period. One patient in the intervention

Table 1: Baseline characteristics of insulin-requiring diabetic patients

Characteristic	Study group: Standard care *n = 23*	Study group: Intervention *n = 23*	*p* value
Mean age (and SD), yr	50 (14.8)	47.5 (11.8)	NS
Sex, no. (and %) of women	11 (48)	13 (56)	NS
No. (and %) with type 1 diabetes	12 (52)	14 (60)	NS
Mean duration of diabetes (and SD), yr	19.2 (7.9)	14.7 (9.2)	NS
Mean duration of insulin therapy (and SD), yr	13.7 (8.4)	10.2 (8.9)	NS

Note: SD = standard deviation, NS = not significant.

group received laser therapy for retinopathy during the study period, and another, who had already lost some digits because of diabetes, underwent additional digital amputations.

Details of therapy are available only for the intervention group, as we did not want to affect the usual care that the standard-care group was receiving. The mean insulin dose (and SD) received by the intervention group was 49.5 (23.2) units at the start of the study and 65.7 (33.9) units at the end of the study. The mean insulin dose for the standard-care group was 58.3 (25.2) units at the start of the study, and there was no significant change in this dose over the study period (the mean dose for this group at the end of the study was 59.3 [27.4] units). There was no correlation between the total insulin dose or the increase in insulin dose for the intervention group and the degree of improvement in HbA_{1c} level. At the beginning of the study 1 patient (4%) in the intervention group was receiving 1 injection per day, 15 (65%) were receiving 2 injections, 5 (22%) were receiving 3 injections, and 2 (9%) were receiving 4 injections. The only change was that for 3 patients the number of daily injections was increased from 2 to 3 because of nocturnal hypoglycemia occurring when the intermediate-acting insulin was given at suppertime; this problem was eliminated when the insulin was given at bedtime. There was no correlation between the number of injections and improvement in HbA_{1c} levels.

Four severe hypoglycemic reactions were reported in patients in the intervention group. Although severe hypoglycemia also occurred in the standard-care group, the frequency was not reliably documented.

Mean body weight (and SD) was not significantly different for the 2 groups at the outset of the study (77 [14] kg for the standard-care group and 76 [16] kg for the intervention group). Over the study period the mean weight gain for the intervention group was 4 kg; there was no weight gain for the standard-care group.

Interpretation

Insulin adjustment by a diabetes nurse educator was an effective method of improving glucose control over a 6-month period in insulin-requiring patients. The reduction in HbA_{1c} was similar to that observed in previous studies, as was the lack of improvement in the group receiving standard care.[1–3,8] This success was accomplished in the setting of a typical hospital diabetes clinic with patients in whom previous attempts to improve glucose control had been unsuccessful. The improvement in glucose control was not due to simply increasing the insulin dose or the number of injections. The patients reported that the key factor in their improvement was the frequent contact with a caring and knowledgeable diabetes educator.

Aubert and colleagues[11] have recently published similar findings for a primary care setting for patients who initially had good glucose control and were receiving oral agents. Our study differed in that it included only patients who were receiving insulin and in whom standard therapeutic approaches had been unsuccessful. Furthermore, we did not experience the high rate of loss to follow-up reported by Aubert and colleagues.

The documented frequency of severe hypoglycemia in the intervention group was 4 episodes in 11.5 patient-years of therapy, similar to that reported by others.[1,3,5]

Administration of insulin and regular monitoring of blood glucose are expensive, and most Canadian patients have to pay for most of these supplies. We were somewhat surprised, therefore, that eliminating the cost of supplies was not associated with improvements in glucose control in the standard-care group.

Our study had some potential limitations. The intervention was very time consuming for the nurse educator, which raises questions about the expense of such a program if it were to be implemented on a continuing basis. Although we did not do a formal cost analysis, there is evidence that replacing physicians with nurses for some aspects of diabetes care can reduce costs as well as improve glucose control.[12] Higher HbA_{1c} levels have been directly associated with higher health care costs.[13] Wagner[14] pointed out that a system using nurse case managers for all diabetic patients is probably not affordable and suggested that such a system be limited to high-risk patients.[14] Our study shows that the nurse educator approach can be effective in even the highest-risk group.

Our study was conducted in a diabetes clinic in a teaching hospital, and it is possible that similar results could not be achieved in smaller clinics. However, because our intervention involved only a single change to published recommendations[15] — telephone contact with the diabetes nurse educator — we believe that this approach would probably produce similar results in most diabetes clinics.

Our study was short and involved a single nurse and a small number of patients. In other studies optimal glucose control has been achieved by 6 months and maintained for years.[1–5,8] We did not formally assess the degree of motivation in each group at the beginning of the study. It is possible that the nurse in our study was uniquely qualified and that, for organizational reasons, equivalent results might not be achieved with larger numbers of patients. These issues need to be addressed in future studies.

Table 2: Levels of glycated hemoglobin (HbA1c) over the course of the study

	Study group; mean proportion of HbA_{1c} (and SD)		
Time	Standard care *n = 23*	Intervention *n = 23*	*p* value*
Baseline	0.094 (0.008)	0.096 (0.010)	ns
6 mo	0.089 (0.010)	0.078 (0.008)	< 0.01
p value†	ns	< 0.001	

*Standard-care group compared with intervention group.
†Baseline compared with 6-month point.

Because conventional methods of delivering diabetes care are ineffective in achieving good glucose control, we believe that the approach we have described represents a potentially important advance in how health care can be delivered to patients receiving insulin.

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Competing interests: None declared for Dr. Sheps. Dr. Thompson has received fees from Eli Lilly and Co. for speaking on topics unrelated to this study.

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