INTENSIFIED TREATMENT OF TYPE 1 DIABETES: PROSPECTIVE EVALUATION AT ONE YEAR OF A THERAPEUTIC PATIENT EDUCATION PROGRAMME

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SUMMARY - Background: Type 1 diabetes treatment requires not only an intensive insulin regimen, but also intensive management, which daily involves participation of the patient. Our aim was to prospectively evaluate the efficacy on patient skills and metabolic control of our routine 5-day in-patient education programme.

Methods: Over one year, each type 1 diabetic patient undertaking the programme for the first time, and able to complete a 2, 6, and 12 month follow-up, participated in the study (n = 76). At baseline (T0), 61 patients had intensified insulin treatment and 15 increased from 2 to 3 daily insulin injections during the hospital stay. Using questionnaires and analysis of a glycaemia logbook, we evaluated at T0, T2, T6 and T12 patient skills related to diet, physical exercise, self-monitoring of blood glucose (SMBG), adjustment of insulin doses, and treatment of hypoglycaemia. Metabolic control was evaluated at the same time.

Results: At one year, the following skills improved: Intake of carbohydrates (T0: 59%, T12: 90% of patients, p < 0.001) and snacks (p < 0.001), appropriate physical exercise (p < 0.001), frequency of SMBG (T0: 3.3 ± 1.5/day, T12: 4.5 ± 1/day, p < 0.001), frequency of post-prandial tests (p < 0.001) and adjustment of insulin doses (T0: 16%, T12: 53% of patients, p < 0.001).

More patients always carried sugar (T0: 61%, T12: 97%, p < 0.001) and appropriately treated hypoglycaemia (T0: 48%, T12: 79%, p < 0.001). Concurrently, HbA1c decreased (T0: 8.8 ± 1.5%, T12: 7.7 ± 0.9%, p < 0.001), and the frequency of hypoglycaemia was reduced (p < 0.001). There was a correlation between the decrease of HbA1c and the frequency of SMBG (p < 0.001, r² = 0.24).

Conclusions: Education led to positive changes in patient skills, which were maintained over one year and were associated with improved metabolic control.

Key-words: education, type 1 Diabetes, patient skills, self-monitoring of blood glucose, metabolic control.
The achievement and maintenance of near-normal glycaemic control, in order to prevent the incidence and progression of long-term complications, is one of the key therapeutic goals of the treatment of type 1 diabetes, and an intensive insulin regimen by multiple daily injections has proven its effectiveness in lowering glycaemic levels [1]. However, intensification of the insulin regimen is not sufficient to maintain globally satisfactory glycaemic control. Intensive insulin therapy fails to maintain near-normal glycaemia without the association of intensified SMBG and reinforced follow-up [2]. Moreover, the attempt to achieve normoglycaemia may lead to the risk of a dramatic increase in the frequency of hypoglycaemia. Avoidance of severe hypoglycaemia and control of the frequency of mild hypoglycaemia are associated key objectives of diabetes management, taking into account patient safety and quality of life.

Glycaemic control requires daily involvement by the patient in the management of an intensified treatment. This management includes not only the adjustment of insulin therapy guided by SMBG, but also various appropriate skills concerning diet, physical exercise, and hypoglycaemia. Providing the patient with the ability to develop such appropriate skills, education programmes are part of the treatment, and their effectiveness has to be evaluated. Most studies concerning education do not permit clear evaluation of the education programme, because of various limitations: the programme itself is not precisely described, the heterogeneous population includes type 1 and type 2 diabetic patients, and the evolution of behaviours is not analysed [3-6], since evaluation focuses preferentially on metabolic control. Prospective studies evaluated a 5-days education programme in type 1 diabetic patients [7-10]. They all reported the effects on metabolic control, some of them evaluated global knowledge [7-9], but they usually did not examine an opened panel of self-management skills. In this study, we prospectively evaluated during one year our routine 5-day education programme for type 1 diabetic patients. Our primary goal was to determine the evolution of metabolic control. In addition, we analysed the impact of our education programme on a large range of decisive skills for global management of type 1 diabetes.

**PATIENTS AND METHODS**

**Patients**

From November 1996 to November 1997, patients with type 1 diabetes undertaking our education programme were invited to participate in the study. The two exclusion criteria were:

- patients who had previously completed a structured education programme;
- patients who were not able to complete a 2, 6 and 12 month follow-up in our hospital, for geographical reasons.

According to these objective criteria, 76 patients out of 197 were proposed to participate in the study, and all of them accepted. We included 40 women and 36 men, age 34.6 ± 11.7 years, duration of diabetes 10.5 ± 10.2 years.

During the 6 months before inclusion, patients had consulted their diabetologist almost twice (1.8 times), and this frequency of visits remained the same during the study period.

**Therapeutic education programme**

Our programme is designed for groups of 8 patients, during a 5-day hospital stay. The curriculum combines individual and group formation sessions, run by a multiprofessional team. Pedagogic tools and interactive education methods are used, as recommended [11]. The 22 hours of group sessions are structured around several themes, including diet, physical exercise, insulin therapy management, prevention of acute events.

Therapeutic objective was near-normoglycaemia (3.9 < G < 6.7 mmol/L before meals, 6.7 < G < 8.9 mmol/L 2 hours after meals). Hypoglycaemia threshold was G ≤ 3.3 mmol/L. Patients were recommended:

- to eat carbohydrates at each meal, to have a well balanced daily intake (35% carbohydrate, 35% protein, 15% fat) and to take 2 snacks per day. Carbohydrate equivalences were taught;
- to practice throughout the year an endurance physical exercise, at least three times a week for 45 minutes;
- to check their capillary blood glucose 4 to 6 times per day, and to record all results in a logbook;
- to adjust insulin doses, according to anticipated carbohydrate intake and physical exercise (anticipation method), and according to the analysis of capillary glycaemia in the previous days (logbook analysis method, [12]). Patients were discouraged from increasing or decreasing their insulin dose solely according to the immediate pre-injection glycaemia (compensatory method);
- to have an appropriate intake of sugar in case of hypoglycaemia, plus carbohydrate if it occurs far from a meal. Patients were told to always carry sugar with them.

**ABBREVIATIONS**

SMBG : Self-Monitoring of Blood Glucose
DCCT : Diabetes Control and Complications Trial
EDIC : Epidemiology of Diabetes Interventions and Complications research group study
Education is associated with a global therapeutic strategy, including optimisation of intensive therapy using multiple insulin injections.

Study Design

During this prospective cohort study, patients were evaluated at baseline, and 2, 6, and 12 months after the education programme. At each time, the same examiner evaluated patient skills and metabolic control.

Using questionnaires and analysis of the blood glucose self-monitoring logbook, we evaluated patients’ abilities and skills related to the following topics: diet, physical exercise, glycaemic objectives, blood glucose monitoring, adjustment of insulin doses and treatment of hypoglycaemia.

Physical exercise was assessed by a specific score, taking into account the recommendations described above.

To analyse more precisely the adjustment of insulin doses, we took into account the method that they preferentially used, and considered separately: patients who never adjust their insulin doses; patients using the compensatory method; patients using anticipation and/or logbook analysis method; patients using alternatively one method or another (unclassifiable patients).

The incidence of ketoacidosis or severe hypoglycaemia (i.e., requiring external help, according to the DCCT, 1), was recorded at each visit. The number was compared with the previous one-year period. Frequency of mild hypoglycaemia took into account the number of values = 3.3 mmol/L reported in the logbook during the previous 14 days, a period of time considered as sufficient to reflect the frequency of hypoglycaemia.

HbA1c was measured by high-performance liquid chromatography (HPLC), normal range 4-6%.

Statistical analysis

Statistical analysis was carried out using STATVIEW software (Abacus Concepts Inc, Berkeley, CA, USA). Results are expressed as mean±sd. The evolution of time-related continuous criteria was tested using ANOVA for repeated measures. Relationship between variables was assessed by estimating Pearson’s correlation coefficients which, moreover, we tested against zero. The significance threshold of the tests was 0.05.

Results

Patient follow-up

We included 76 patients. During follow-up, 73 patients (96.1%) were evaluated at 2 months, 71 patients (93.4%) at 6 months, and 70 patients (92.1%) at one year.

Insulin regimen

At baseline (T0), 61 patients had intensive treatment by multiple daily injections, combining short-acting and NPH insulin. The remaining 15 patients who were on conventional insulin therapy at baseline increased their daily injections from 2 to 3 during the 5-day hospital stay. During follow-up, neither mean daily insulin dose, nor number of daily injections were significantly modified (U per day/number of injections per day: T0: 42/2.9; T2: 45/3.1; T6: 42/3.1; T12: 41/3.2; NS).

Patient knowledge and skills

In the course of the study, the number of patients having appropriate knowledge or skills related to various diet items improved significantly (Table I). Knowledge and skills related to the management of hypoglycaemia also improved during the year (Table II).

Patients improved their score of physical exercise during the study (TO: 3.1 ± 2.7; T2: 3.7 ± 2.7; T6: 4.1 ± 2.6; T12: 4.2 ± 2.5; p < 0.001). We observed an inverse evolution between the proportion of patients who took appropriate physical exercise (T0: 32%,

Table I. Patient knowledge and skills related to Diet.

<table>
<thead>
<tr>
<th></th>
<th>T0 (%)</th>
<th>T2 (%)</th>
<th>T6 (%)</th>
<th>T12 (%)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intake of carbohydrates at each meal</td>
<td>59</td>
<td>85</td>
<td>92</td>
<td>90</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Appropriate knowledge of carbohydrate equivalences</td>
<td>50</td>
<td>75</td>
<td>80</td>
<td>89</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Well balanced daily intake of carbohydrates, proteins, fats</td>
<td>53</td>
<td>70</td>
<td>78</td>
<td>84</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Intake of one to two snacks per day</td>
<td>63</td>
<td>74</td>
<td>80</td>
<td>83</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Data are percentages of patients.
Knowledge of normal glycaemia improved. More patients gave correct answers for pre-prandial (T0: 8%, T12: 56%, p < 0.001), and post-prandial (T0: 15%, T12: 56%, p < 0.001) normal glycaemia. Concurrently, more patients had appropriate self-defined personal objectives for pre (T0: 12%, T12: 49%, p < 0.001) and post-meal (T0: 25%, T12: 59%, p < 0.001) glycaemia.

Frequency of capillary SMBG increased significantly during the study. It is noteworthy that this improvement concerned not only pre-prandial, but also post-prandial tests (Fig. 1).

At the end of the study, significantly more patients adjusted their insulin doses, compared to baseline. Interestingly, patients developed preferentially anticipation and logbook analysis methods. The number of unclassifiable patients did not significantly vary (Fig. 2).

**Metabolic Control**

During the one year follow-up, acute complications were less frequent than during the previous year: se-
vere hypoglycaemia tended to decrease (n/patient-year, T0: 0.4 ± 0.01; T12: 0.2 ± 0.02; NS) and hospitalisations for ketoacidosis were significantly reduced (n/patient-year, T0: 0.13 ± 0.05; T12: 0.02 ± 0.02; p < 0.01).

Glycaemic control improved significantly throughout this one year period (HbA1c at T0: 8.6% ± 1.5; T2: 8.0% ± 1.1; T6: 7.6% ± 0.9; T12: 7.7% ± 0.9; p < 0.001). This decrease of HbA1c concerned patients who were already on intensive therapy at baseline (T0: 8.8% ± 0.9; T12: 7.6 ± 0.9, p < 0.001), as well as patients who switched from 2 to 3 injections during the hospital stay (T0: 9.0% ± 1.5; T12: 8.0 ± 0.9, p < 0.001).

During the same period of time, the frequency of mild hypoglycaemia (every G ≤ 3.3 mmol/L reported in the logbook and validated by the examiner) significantly decreased (n in the previous 14 days: T0: 5 ± 3.3; T2: 4.1 ± 2.4; T6: 3.7 ± 2.5; T12: 3.6 ± 2.1; p < 0.001).

We observed no significant weight gain (body mass index, kg/m²: T0: 22.6; T12: 22.7; NS).

Throughout the one year study, the improvement of HbA1c correlated strongly with the frequency of home blood glucose monitoring (p < 0.001, r² = 0.24; Fig. 3).

**DISCUSSION**

Our results indicate that a structured education programme, inducing improved patient skills, allows a simultaneous and lasting improvement of HbA1c and hypoglycaemia frequency.

Our study included 76 patients. This number is similar to most education studies [3, 4]. In order to obtain an homogeneous evaluation [13], we included type 1 diabetic patients only. Like many authors, we did not compare our population to a control group. In fact, we consider it unethical to exclude some patients, during one year, from our routine therapeutic education programme [14].

A minority of studies report effects of education during one year or more. Our long term study was prospective and had the advantage of intermediate evaluations at 2 and 6 months, which is unusual [3]. We evaluated multiple parameters, whereas most studies investigate a few items [15]. Moreover, we analysed not only metabolic parameters, but also many behavioral outcomes, which should characterise education studies [16].

Behaviours related to diet and physical exercise are not frequently reported in education studies. A prospective study, which included both type 1 and type 2 diabetic patients, showed a beneficial effect on these two lifestyle parameters, but it was not observed longer than 6 months [17]. Our recommendations concerning diet and physical exercise were in accordance with international consensus recommendations [18, 19]. We observed a significant improvement of both diet and physical exercise skill items, which was sustained during one year.

Significantly more patients knew normal values of pre and post-prandial glycaemia, and, more interest-
ingly, had appropriate self-defined personal glycaemic objectives. This latter item, which is not specifically reported in most education studies, appears essential. It reflects basic and primordial coherence between patient and medical objectives, and may be easily checked during visits.

The frequency of self-monitored capillary glycaemia was counted by the examiner on the patient logbook, and increased up to a mean of 4.5 tests per day. This number is in accordance with the minimum of 4 daily tests recommended in the intensive-therapy group of the Diabetes Control and Complications Trial (DCCT), [1]. It is accepted that type 1 diabetic patients check their blood glucose before each insulin injection [20]. However, intensive treatment includes an injection of regular insulin before each meal, and the adjustment of its dose is proposed to take in account post-prandial tests [20, 21]. The increase in the number of tests, and in particular the post-prandial ones, whose frequency doubled, is a sign of understanding and involvement of our patients in their intensive treatment. Indeed, more patients adjusted their insulin doses, specifically according to anticipation and logbook analysis methods, rather than the compensatory method.

Knowledge and skills related to hypoglycaemia significantly improved throughout the study. The high percentage of patients achieving these various appropriate skills (90% or more for 3 out of 4 items) may explain the lack of increase in the frequency of severe hypoglycaemia, despite an improved $HbA_{1c}$. The improved diet, combined with more active SMBG and insulin adjustment, may participate in the concurrent and significant decrease of both mild hypoglycaemia and $HbA_{1c}$.

Improvement concerns both acute events and long term glycaemic control. Hospitalisations for ketoacidosis were significantly reduced, and severe hypoglycaemia tended to decrease. The impact of education on acute events is described in other patient education studies [8, 10]. In particular, 12-15 months after a 5-day hospitalisation education programme followed by a comparable decrease of $HbA_{1c}$, Müller obtained a similar reduction in frequency of ketoacidosis as we did [10]. The incidence of severe hypoglycaemia observed before and one year after education by Müller and by ourselves was comparable. However, the significant decrease that they observed, contrary to us, may be due to the larger number of patients included in their study.

During the year following our education programme, we observed an 0.9% reduction in $HbA_{1c}$, comparable to that observed in other prospective studies [8, 10, 17]. In our study, $HbA_{1c}$ reached the lowest level at 6 months, and then stabilised. Maintenance of glycaemic control improvement longer than 6 months has been observed [10, 17], but fails in most studies [3]. It is noteworthy that decrease of $HbA_{1c}$ was not counterbalanced either by more frequent hypoglycaemia, or by a weight gain, as could have been feared. The frequency of mild hypoglycaemia, on the contrary, decreased significantly throughout the study. This decrease cannot be explained by a change in hypoglycaemia threshold, as each hypoglycaemia was
validated by the examiner as a $\geq 3.3$ mmol/L reported on the log book, at any time of the study. This concurrent improvement of both HbA$_{1c}$ and frequency of hypoglycaemia may have been made possible by the association with intensive insulin therapy of intensive diabetes management, implemented through education [22]. Using a particular strategy of insulin dose adjustment, studies with functional insulin therapy also showed a simultaneous reduction in HbA$_{1c}$ levels and in the frequency of severe hypoglycaemia [23, 24].

Because the decrease of HbA$_{1c}$ was not more marked in patients who switched to intensive treatment during hospitalisation than in the others, we can assume that this improvement is related to several concomitant changes in patient skills after education. We found a correlation between HbA$_{1c}$ and the frequency of self-blood glucose monitoring, but not with the other skill items separately. Some authors found a negative correlation between HbA$_{1c}$ and a global score of knowledge and skills [8], which may be more appropriate than a detailed evaluation to establish a link between skills and metabolic control. A more powerful methodology, or larger-scale studies may be necessary to further investigate how behaviours play a role in metabolic control.

In our study, HbA$_{1c}$ is strongly linked to increased frequency of home blood glucose self-monitoring. Conversely, during the first year of the DCCT/Epidemiology of Diabetes Interventions and Complications Research Group study (EDIC), HbA$_{1c}$ of type 1 diabetic patients on intensive treatment increased from 7.2 to 7.7%, while self-monitoring became lax in almost half of the patients, in comparison with the previous DCCT period [2]. This suggests that, once intensive therapy has been appropriately prescribed, SMBG is an essential guide in the effort to achieve a better glycaemic level. Diabetes management in the EDIC study also differs from the DCCT by the return to routine follow-up, instead of an intensified one. In our study, follow-up was not intensified, and its frequency was similar to that in the conventional-treatment group of the DCCT [1]. A stronger link between HbA$_{1c}$ and SMBG than between HbA$_{1c}$ and the frequency of visits has been described [25]. Moreover, SMBG is accompanied by a lower HbA$_{1c}$ in patients who had completed an education programme, compared with those who had not [26]. Indeed, the increase of blood glucose self-monitoring that we observed, in correlation with decreased HbA$_{1c}$, appears to be an effect of the involvement of an educated patient. These results are consistent with the findings of Bott et al., who observed concurrent positive changes of HbA$_{1c}$, SMBG and some psychosocial factors believed to be associated with active self-management, in type 1 diabetic patients after an education programme [27].

In conclusion, one year after our education programme, intensive management of diabetes, enabled by various and sustained changes in patient skills, is associated with improved HbA$_{1c}$, which is not counterbalanced by more frequent hypoglycaemia or weight gain.

Acknowledgments – We thank J.P. CHARLET, MD, for his contribution to statistical analysis.

S. LEMOZY-CADROY AND S.CROGNIER have contributed equally to the work.

REFERENCES


