Targeting Blood Glucose Management in School Improves Glycemic Control in Children with Poorly Controlled Type 1 Diabetes Mellitus

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We hypothesized that school nurse supervision of glucose and insulin-dose adjustment significantly improves the hemoglobinA1c (HbA1c) level in pediatric patients with poorly controlled type 1 diabetes mellitus (HbA1c ≥ 9%). A total of 36 subjects were enrolled and 18 subjects were randomized to receive the 3-month intervention. Their average HbA1c was lowered by 1.6%, suggesting that this intervention helps this difficult group of patients. (J Pediatr 2008;153:575-8)

Poorly controlled type 1 diabetes mellitus (T1DM) occurs for numerous reasons. Deviation from self-diabetes care is associated with poor control. One study found that 29% of the adolescents studied fabricated their blood glucose (BG) values because they did not check their BG, and 25% reported missing insulin injections.1 Therefore, supervision of insulin administration as a strategy to improve glycemic control must be targeted. School nurses serve as an important resource, caring for the children’s medical needs when at school. Previous studies show that they make a difference in children with asthma.2 In this study, we tested the hypothesis that supervised BG monitoring and insulin injections at school will improve glycemic control in children and adolescents with poorly controlled T1DM.

METHODS

Subjects

The Baylor College of Medicine Institutional Review Board approved the study protocol. A total of 36 subjects with high hemoglobin A1c (HbA1c) were recruited. The patients and their parents provided assent and consent per institutional guidelines during the screening visits. The subjects were randomized to either the control group or the intervention group to begin the study at the second visit, which occurred within 3 months of the screening visit. After 3 months in the study, subjects returned for the third and final visit. The Table summarizes baseline clinical characteristics of the 2 groups at the second visit.

Intervention Group

At the second visit, all subjects started insulin glargine (Lantus; Sanofi-Aventis, Bridgewater, New Jersey) and insulin aspart (Novolog FlexPen; Novo Nordisk, Princeton, New Jersey) (Figure). The subjects, parents, and school nurses were instructed in the use of insulin aspart pens and the OneTouch Ultra glucometer (LifeScan, Milpitas, California). The school BG records, generated by an automatic, long-range, wireless BG monitoring and transmittal system (GlucoMON; Diabetech, Dallas, Texas), were reviewed weekly, and the subjects’ insulin doses were adjusted as necessary. The intervention subjects received insulin glargine vials with insulin syringes, insulin aspart pens with needles, a OneTouch Ultra glucometer with strips, and access to the GlucoMON system free of charge (funded by the study grant).

| BG | Blood glucose |
| HbA1c | Hemoglobin A1c |
| NPH | Neutral protamine Hagedorn |
| T1DM | Type 1 diabetes mellitus |
| IIM | Intensive insulin management |

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Control Group

The control subjects were instructed to continue their usual diabetes care and insulin regimen (Figure). Their insulin and supplies continued to be covered by their insurance carriers. Because all of the control subjects had medical insurance, they likely had their needed medications and supplies; however, they did not have access to the GlucoMON system.

Measurements

HbA1c level was measured in each subject at the second and final visits. Hypoglycemia was defined as blood glucose ≤59 mg/dL. Weight gain was measured as body mass index (BMI, in kg/m²) and BMI z-score.

Statistics

HbA1c level and other clinical characteristics were analyzed using GraphPad Prism 4 software (GraphPad, San Diego, CA). Comparison of the measured outcomes and clinical characteristics between the 2 groups was done using unpaired t-tests. Comparison of the ratios (male vs female or mix-split vs intensive insulin management [IIM]) was done using Fisher’s exact test. A P value <.05 was considered statistically significant.

RESULTS

Primary Outcomes

At the end of the 3-month study period, the HbA1c level remained unchanged in the control group but was decreased significantly in the intervention group (Table).

Adverse Events

Hypoglycemia. No BG records were available for the control group, because these subjects did not bring their BG logbooks to their visits as required. For the intervention group, the rate of hypoglycemia (BG < 59 mg/dL) was 0.86 ± 0.55 episode/patient-week. One subject who had a history of hypoglycemic seizure before enrollment experienced a morning hypoglycemic seizure during the trial. Another subject reported an altered morning mental status that was treated successfully with glucagon at home. Both of these subjects did not experience any further severe hypoglycemic episodes after their insulin doses were decreased appropriately. There was no correlation between the rate of hypoglycemia and the change in HbA1c level (r = 0.17).

Weight Gain. There was no difference in BMI between the 2 groups either before or after the 3-month study period. There was no correlation between the change in BMI and the change in HbA1c level in the intervention group (r = 0.24).

Diabetic Ketoacidosis. During the study period, 1 subject in the control group and 3 subjects in the intervention group went to the emergency room for treatment of hyperglycemia and ketosis.

Table. Subjects’ clinical characteristics at the beginning and the end of the 3-month study

<table>
<thead>
<tr>
<th>Clinical characteristic</th>
<th>Control (n = 16)</th>
<th>Intervention (n = 18)</th>
<th>Control (n = 16)</th>
<th>Intervention (n = 18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>14.0 ± 1.7 (11.0 to 16.0)</td>
<td>13.3 ± 1.7 (10.0 to 17.0)</td>
<td>13.5 ± 1.7 (12.0 to 14.0)</td>
<td>13.8 ± 1.7 (11.0 to 15.0)</td>
</tr>
<tr>
<td>Sex, males/females, n</td>
<td>7/9</td>
<td>10/8</td>
<td>10/6</td>
<td>14/4</td>
</tr>
<tr>
<td>Insulin regimen, mix-split/IIM</td>
<td>6.5 ± 2.8 (3.0 to 12.7)</td>
<td>5.3 ± 4.4 (1.1 to 15.2)</td>
<td>6.2 ± 3.0 (4.0 to 20.0)</td>
<td>5.8 ± 4.7 (0.6 to 20.0)</td>
</tr>
<tr>
<td>T1DM duration, years</td>
<td>11.2 ± 3.0 (9.0 to 13.0)</td>
<td>10.8 ± 3.0 (9.0 to 12.0)</td>
<td>11.5 ± 3.0 (9.0 to 14.0)</td>
<td>11.2 ± 3.0 (9.0 to 13.0)</td>
</tr>
<tr>
<td>Insulin, U/kg/day</td>
<td>2.37 ± 0.34 (1.7 to 3.2)</td>
<td>2.78 ± 0.97 (0.5 to 2.1)</td>
<td>2.37 ± 0.34 (1.7 to 3.2)</td>
<td>2.78 ± 0.97 (0.5 to 2.1)</td>
</tr>
<tr>
<td>BMI</td>
<td>23.7 ± 4.1 (18.7 to 32.3)</td>
<td>21.7 ± 2.9 (16.4 to 28.4)</td>
<td>23.7 ± 4.1 (18.7 to 32.3)</td>
<td>21.7 ± 2.9 (16.4 to 28.4)</td>
</tr>
<tr>
<td>BMI z-score</td>
<td>0.97 ± 0.77 (0.06 to 1.7)</td>
<td>0.67 ± 0.74 (0.05 to 2.1)</td>
<td>0.97 ± 0.77 (0.06 to 1.7)</td>
<td>0.67 ± 0.74 (0.05 to 2.1)</td>
</tr>
</tbody>
</table>

Data are expressed as mean ± SD and (range).
DISCUSSION

In this study, we found that supervised BG monitoring, insulin glargine injections, and periodic appropriate insulin dose adjustment in the school setting improved the HbA1c level in children and adolescents with poorly controlled T1DM. Our findings are comparable to those of a previous retrospective study of similar interventions. Other interventions, such as insulin pump and real-time continuous glucose monitoring, also have been found to improve (albeit to a lesser extent) the HbA1c level in children and adults with poorly controlled diabetes.

Hypoglycemia was seen in the intervention group because the school nurses measured BG values at lunchtime. Hypoglycemic episodes were expected in those subjects receiving IIM, and the rate of the hypoglycemia seen in this study was similar to that reported previously. The rate of hypoglycemia in the control group is not known, because these subjects either failed to bring their logbooks or did not adequately monitor blood glucose concentrations.

A limitation of this study is that it fails to distinguish whether any of the individual components of the intervention or all of the components collectively accounted for the observed improvement in HbA1c level. Intuitively, direct observation of BG monitoring and insulin injections would tend to improve glycemic control by eliminating fabrication of BG values and missing insulin injections, as was demonstrated in a previous study. In those subjects taking neutral protamine Hagedorn (NPH) insulin mixed with a rapid-acting insulin twice a day and routinely miss morning injections, the switch to insulin glargine given at lunchtime would provide better basal insulin coverage compared with NPH taken once a day. Telemedical support, which allows timely transmission of BG records and insulin dose adjustments, has been shown to improve HbA1c levels in adolescents and adults with T1DM.

Another limitation of our study is its short duration. The study design was kept short because we needed to administer the intervention when school was in session. We chose the parallel trial instead of a crossover design for this pilot study because we were concerned about the possible high dropout rate in this difficult patient population. Further clinical trials are currently planned to determine which component of our intervention is the most beneficial and whether this intervention has long-term sustainability.

Despite its limitations, this pilot study suggests an effective short-term strategy for managing children and adolescents with poorly controlled T1DM.
We thank the patients and their families for participating in this study, the faculty at Texas Children’s Hospital Diabetes Center for referring the patients for this study, and Dr E. O’Brian Smith for providing statistical assistance. We appreciate the essential and invaluable participation of the school nurses in our study and their incredible dedication to caring for children with diabetes at their schools.

REFERENCES