Self-Management Competence as a Predictor of Outcomes of Intensive Therapy or Usual Care in Youth With Type 1 Diabetes

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OBJECTIVE — This article evaluates prediction of HbA_{1c} during an 18-month randomized trial of intensive therapy (IT) versus usual care (UC) for type 1 diabetes in 142 youth.

RESEARCH DESIGN AND METHODS — Patients received a composite score for self-management competence (SMC) that combined standardized scores on baseline measures of diabetes knowledge, treatment adherence, and quality of health care interactions. They were categorized by tertiles split into low, moderate, and high SMC levels.

RESULTS — IT yielded very similar mean HbA_{1c} levels in all three SMC groups. However, in UC patients, HbA_{1c} increased markedly for low-SMC youth but not for moderate- and high-SMC youth during the trial. Compared with the mean HbA_{1c} of their UC counterparts, low-SMC patients realized greater glycemic benefit from IT than did the moderate- or high-SMC youth. Baseline SMC was more strongly correlated with HbA_{1c} for UC than IT.

CONCLUSIONS — All three SMC groups realized similar glycemic benefits from IT. The mean HbA_{1c} levels of low-SMC patients in the UC group increased markedly over 18 months, whereas HbA_{1c} levels of low-SMC patients in the IT group did not differ significantly from that of moderate- and high-SMC patients. Relative to their UC counterparts, low-SMC patients derived greater glycemic benefit from IT than did moderate- or high-SMC youth. SMC may be more critical to the success of UC than IT. Perhaps more importantly, patients should not be denied access to IT on the basis of limited competence in diabetes self-management.

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The Diabetes Control and Complications Trial (DCCT) and the Epidemiology of Diabetes Interventions and Complications (EDIC) study proved that maintenance of excellent glycemic control through intensive therapy (IT) delays the onset and slows the progression of long-term complications of type 1 diabetes by 50–75% and that these benefits are durable (1–3). The 1,441 DCCT patients included only 195 carefully selected adolescents (>13 years old at randomization), most of whom were young adults by the end of the study (1). Although the benefits of IT may apply to adolescents and adults, IT is more difficult to implement in adolescents (1–3). Extrapolating adolescents' IT results to the preadolescent type 1 diabetes population is unjustified. Thus, the DCCT's relevance to management of pediatric type 1 diabetes has not been confirmed. The American Diabetes Association has encouraged targeting near-normal HbA_{1c} for all patients with type 1 diabetes unless there are compelling safety concerns (3). Elsewhere, we have reported the results of an 18-month trial of IT versus usual care (UC) for youth with type 1 diabetes. In that trial, IT patients maintained a mean HbA_{1c} of 7.8%, compared with 8.6% for UC patients, with no significant difference in severe hypoglycemia or weight gain between groups (4).

Along with more frequent insulin injections or use of an insulin pump, IT includes much more professional involvement with patients than UC and is therefore more costly (1,2). Methods of reducing the cost or enhancing the outcomes of IT would be valuable, such as decreasing treatment failures by offering IT to patients who are most likely to benefit. Hence, this article evaluates prediction of benefit from IT or UC among patients in the above trial.

This article introduces an index of diabetes self-management competence (SMC) that incorporates several elements of effective family management of type 1 diabetes in children. These include measures of treatment adherence, diabetes knowledge, and quality of health care interactions. Scores on these measures obtained from parents and youth with diabetes were standardized and combined into a composite index of SMC. We then examined whether the families' baseline SMC predicted glycemic control during 18 months of treatment. Our hypothesis was that patients with moderate SMC would benefit more from IT than would those with either high or low SMC,

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Abbreviations: DCCT, Diabetes Control and Complications Trial; DISC, Diabetes Information Survey for Children; DSMP, Diabetes Self-Management Profile; IT, intensive therapy; PSQ, Physician Satisfaction Questionnaire; SMC, self-management competence; UC, usual care.
A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

See accompanying editorial, p. 2204.

since patients with moderate SMC possess some prerequisite self-management skills while also having room for glycemic improvement.

RESEARCH DESIGN AND METHODS

Recruitment of participants

Families were recruited for the study and received type 1 diabetes care at Children's Hospital at Washington University in St. Louis, Missouri, or Nemours Children's Clinic in Jacksonville, Florida. Before a clinic appointment, families of potentially eligible youth received a letter about the study signed by the child's endocrinologist and the principal investigator. Then, the trial coordinator telephoned parents to verify the youth's eligibility, answer questions about the study, and offer to meet with the family to discuss the project.

To be eligible, youth must have been at least 6, but not yet 16, years old, diagnosed with type 1 diabetes at least 2 years or at least 1 year with a negligible stimulated C-peptide level, free of other chronic diseases except well-controlled Hashimoto thyroiditis or well-controlled asthma and with apparently normal cognitive development. Patients on IT regimens (as defined below) were ineligible for enrollment. Youth with type 1 diabetes were required to reside in a family situation and to expect to remain there throughout the study, to have telephone service, and to plan to continue to receive diabetes therapy at the enrolling center throughout the study. Caregivers had to be literate in English and they could not have been treated for psychosis, major depression, bipolar disorder, or substance use disorder in the prior 6 months. Youth with type 1 diabetes could not have been a psychiatric inpatient in the prior 6 months. Biological parents and stepparents living with the patient were expected to participate, whereas other adult caregivers residing in the home were allowed to participate.

A total of 446 families were contacted, of whom 147 (31%) agreed to participate. Reasons for refusal included travel distance, scheduling difficulty, reluctance about regimen demands, and hesitance to defer insulin pump therapy if randomized to UC. Soon after randomization, 5 families withdrew from the study (2 IT and 3 UC), leaving a sample of 142 patients and families who contributed data for this report.

Experimental design and treatment regimens

Youth were randomized to 18 months of either UC or IT, as described below. Randomization was stratified by the patients' age and HbA_{1c} to promote equivalence of the groups. Because the central questions in this study were whether, and under what conditions, youth with type 1 diabetes benefit from the added professional support and resources entailed in IT, the design did not include an attention control group for the increased professional contact with the IT group. Study measures were collected at a baseline evaluation before randomization, at quarterly evaluations, or at comprehensive evaluations at 9 and 18 months later. Reports of HbA_{1c}, severe hypoglycemia, hospitalizations, emergency room care, and treatment fidelity were given twice annually to an advisory panel of three pediatric endocrinologists who were not affiliated with either center.

UC. UC patients ($n = 70$) received the standard type 1 diabetes therapy offered at the two study sites during 1997–2001. This regimen included the following glycemic targets: $HbA_{1c} \leq 8.0\%$, average preprandial blood glucose between 70 and 140 mg/dl, average postprandial blood glucose <180 mg/dl, 3:00 A.M. blood glucose >65 mg/dl, and avoidance of recurrent or severe hypoglycemia. Treatment included two or three daily subcutaneous insulin injections, three or four daily blood glucose tests, quarterly clinic visits with a pediatric endocrinologist and diabetes nurse, annual clinic visits with a dietitian and a psychologist, and participation in systematic diabetes education (5).

IT. Patients and families randomized to IT ($n = 72$) were offered as much multidisciplinary support as needed to achieve, to the degree attainable, HbA_{1c} <6.5%, average preprandial blood glucose between 70 and 120 mg/dl, average postprandial blood glucose <150 mg/dl, 3:00 A.M. blood glucose >65 mg/dl, and avoidance of recurrent or severe hypoglycemia. The regimen included three or more daily insulin injections or use of an insulin pump, four to six daily blood glucose tests, weekly 3:00 A.M. blood glucose tests, weekly telephone contact with a diabetes nurse, access to the services of a dietitian and a psychologist without charge, monthly clinic visits with the diabetes nurse and quarterly clinic visits with a pediatric endocrinologist, advanced diabetes education, and access to a monthly multifamily diabetes support group.

Participation incentives

Efforts were made to optimize recruitment and retention. Participants earned $50 each upon completing evaluations at baseline, 9 months, and 18 months, up to $300 per family during the study. After each quarterly visit, families received approximately $100 worth of diabetes supplies to ensure that lack of supplies did not impede type 1 diabetes management. Evaluations were scheduled at the convenience of the family. UC families were offered 6 months of IT from study personnel at no cost after completing the 18-month trial.

Measures

Various measures were collected before, during, and at the end of the study, including treatment outcomes and predictors. Only measures analyzed for this article are described here. Parents reported demographic information, the child's medical history, and data needed for the Hollingshead Four-Factor Index of Social Status (6).

SMC was assessed using measures of diabetes knowledge, treatment adherence, and quality of health care interactions. The Diabetes Information Survey for Children (DISC) is a 98-item test of diabetes knowledge for use with 6- to 17-year-old youth and parents (7). The DISC measures knowledge of diet, exercise, insulin, blood glucose testing, and pathophysiology of type 1 diabetes. Administration to children <11 years old was by interview; older participants completed a written form. Previous work has confirmed the DISC's split-half reliability (0.92), test-retest reliability over 4 weeks (0.88), convergent validity, and construct validity (7).

The Diabetes Self-Management Profile (DSMP) is a 23-item structured interview that assesses five domains of type 1 diabetes self-management: exercise, diet, blood glucose testing, management of hypoglycemia, and insulin administration/adjustment. It was administered to youths ≥11 years old separately from

Table 1—*Sample characteristics*

	IT	UC
Youth's age (months)	134.3 ± 32.6	138.1 ± 31.8
Duration of diabetes (months)	57.0 ± 34.3	50.7 ± 31.9
Hollingshead socioeconomic index	43.1 ± 11.9	43.6 ± 12.7
HbA_{1c} (%)	8.3 ± 1.1	8.3 ± 1.1
Sex* (%)		
Male	65	47
Female	35	53
Race/ethnicity (%)		
Caucasian	89	86
African American	10	11
Hispanic	0	1
Other	1	1
Family composition (%)		
Both biological parents	72	71
One biological and one stepparent	11	4
One biological parent only	15	24
Other	2	1

Data are means ± SD, unless otherwise noted. *The IT group included significantly more male than female subjects ($P < 0.05$). No other differences between the groups were statistically significant.

parents, or to parents and younger children together. Total scores for this sample possess internal consistency of 0.76. Validation data have been published (8).

The Physician Satisfaction Questionnaire (PSQ) is a 20-item scale completed by a health care provider immediately after a clinic visit that rates the quality of the patient-provider relationship, adequacy of collection of clinical information, and efficiency of the visit (9). Health care providers were aware of each youth's treatment regimen. Internal consistency of the total scale (coefficient α) was 0.94 for this sample.

HbA_{1c} was the primary index of glycemic control. It was estimated with a DCA2000+ system (Miles Laboratories), which measures HbA_{1c} using a specific monoclonal antibody and a turbidimetric assay. Patients tested blood glucose daily using a meter with memory, which was brought to each visit for download and analysis. Parents maintained a Severe Hypoglycemia Diary to report the occurrence, management, and outcome of hypoglycemia that met any of these criteria: *1*) occurrence of a seizure or loss of consciousness; *2*) assistance of another person required to interrupt the episode, *3*) an episode requiring administration of glucagon or intravenous dextrose under the direction of a health professional, or *4*) treatment by an emergency medical services squad or transport to an emergency room. Parents were asked to report these events to study staff as soon as possible after the episode. Other medical variables recorded were hospitalizations, emergency room admissions, height, weight, BMI, linear growth velocity, and Tanner stage.

Calculation of family composite scores for SMC. SMC was defined as those skills needed for effective family management of type 1 diabetes. Three component skills were measured and incorporated into a composite SMC index for each family: diabetes knowledge (DISC) (7), treatment adherence (DSMP) (8), and the quality of health care interactions (PSQ) (9). Scores obtained by youth, mothers, fathers, and health care providers on these measures were positively correlated with one another ($r = 0.17$–0.66, $P < 0.05$) and with the SMC composite, except that the youths' scores on the DISC failed to correlate significantly with scores on the DSMP and the PSQ. Scores on each measure were transformed into standardized T-scores based on data from this sample (mean 100 ± 15). T-scores for family diabetes knowledge and treatment adherence were derived by first averaging the standardized scores for family members who completed the DISC (7) or the DSMP (8), respectively. Family T-scores for diabetes knowledge, treatment adherence, and quality of health care interactions were summed and averaged, yielding an SMC composite score. Based on a tertile split of resultant SMC scores, families were categorized as low, moderate, or high SMC.

RESULTS

Sampling plan

Table 1 illustrates the demographic similarity of the IT and UC groups. The only significant difference was the larger proportion of male than female subjects in IT. Children in the low-SMC group were older, more likely to be members of a racial minority, and in families that were smaller and of lower socioeconomic status than those in the other SMC groups.

Psychometric validation of the SMC composite score

With the two groups combined, mean HbA_{1c} during treatment was 8.0% for the high-SMC group, 8.1% for the moderate-SMC group, and 8.6% for the low-SMC group [F (2,140) = 4.67, $P < 0.02$]. At baseline, SMC scores correlated significantly with HbA_{1c} ($r = -0.36$, $P < 0.01$). Temporal stability of the SMC was confirmed by a significant correlation between values obtained at 9-month ($r = 0.55$, $P < 0.0001$) and 18-month ($r = 0.32$, $P < 0.02$) intervals. Internal reliability of the SMC (coefficient α) was 0.82 for this sample at baseline.

Effects of treatment regimen and SMC level on glycemic control

During the 18 months of treatment, HbA_{1c} (mean ± 1 SD) was 7.8 ± 0.9% for IT and 8.6 ± 1.1% for UC. Overall, 6.9% of HbA_{1c} results for the IT group were ≤6.5%, although only one IT patient achieved that level at every follow-up visit.

Figure 1 displays mean HbA_{1c} for IT and UC patients in the three SMC tertiles. For all three baseline SMC levels, IT patients' levels were below those of UC patients. Repeated-measures ANOVA revealed a significant main effect for regimen [F (1,139) = 14.71, $P < 0.0001$], a significant regimen-by-time interaction [F (1,139) = 5.39, $P < 0.01$], and a significant interaction between regimen and SMC level [F (2,138) = 3.37, $P < 0.04$]. Among UC patients, HbA_{1c} differed according to SMC level. Low-SMC patients receiving UC showed a steady increase in mean HbA_{1c} to 9.6% at 18 months. In contrast, the mean HbA_{1c} level for high- and moderate-SMC patients receiving UC did not change significantly during treat-

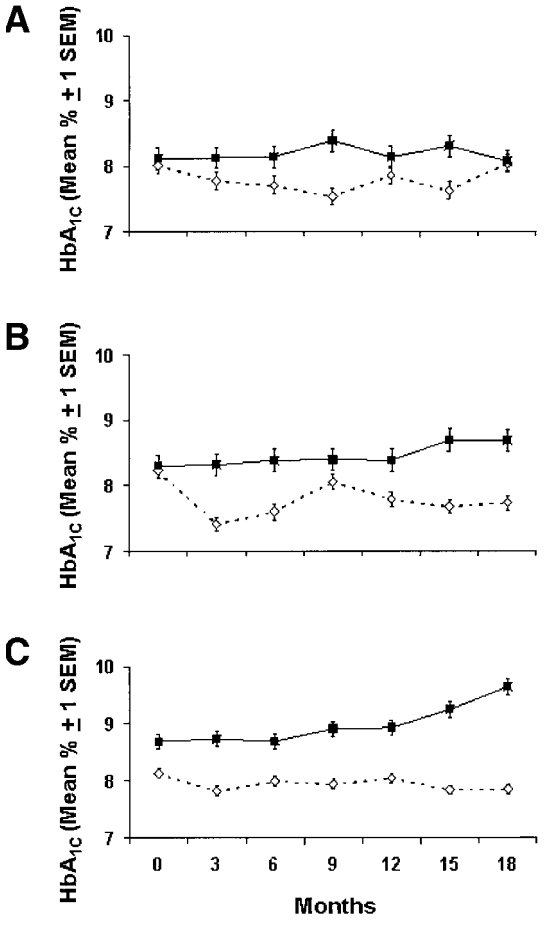

Figure 1—*Quarterly HbA_{1c} levels (mean ± 1 SE) for the IT (◇) and UC (■) groups for patients with high, moderate, and low SMC. A: High SMC. B: Moderate SMC. C: Low SMC.*

ment. For IT, there was no significant effect for SMC on HbA_{1c}, whereas for UC, the main effect for SMC was significant [F (2,69) = 6.26, $P < 0.004$]. Post hoc comparisons indicated no significant differences in HbA_{1c} among SMC groups receiving IT, but significant differences were found among SMC groups receiving UC [F (2,140) = 5.34, $P < 0.01$]. At four of the six follow-ups for UC patients, the low-SMC group had significantly higher HbA_{1c} than either or both of the high- or moderate-SMC groups.

Figure 1 also reveals that, in response to IT, the three SMC groups achieved similar HbA_{1c} during treatment. Mean HbA_{1c} during IT was 7.8, 7.7, and 7.9%, respectively, for the high-, moderate-, and low-SMC groups. Neither the main effect for SMC groups nor the SMC group-by-time interaction were significant. Thus, mean HbA_{1c} levels for the three SMC groups during IT were indistinguishable statistically.

Figure 2 illustrates differences between mean HbA_{1c} levels achieved by the IT and UC regimens in the high-, moderate-, and low-SMC groups over successive 6-month periods. All three groups initially showed modest reductions in mean HbA_{1c} relative to their UC counterparts, but larger differences emerged later. By the end of the 18-month trial, the high-SMC group experienced a negligible decrease in HbA_{1c} of 0.2%, the moderate-SMC group maintained an ~0.8% reduction relative to UC, and the low-SMC group reached a nadir 1.2% below the level of their UC counterparts. Relative to their UC counterparts, the low-SMC group showed more improvement in HbA_{1c} during IT than did the other SMC groups.

Another perspective is provided by Pearson r correlations between baseline SMC scores and HbA_{1c} levels for IT and UC at each follow-up visit. The correlation between baseline SMC and HbA_{1c} was statistically significant for IT ($r = -0.32$, $P < 0.01$) and UC patients ($r = -0.39$, $P < 0.001$), with no significant difference between the coefficients. Once treatment with the two regimens was initiated, the correlations remained comparable to the baseline r value for the UC patients ($r = -0.32$ to -0.40, $P < 0.001$). However, for IT, the correlation between baseline SMC and HbA_{1c} was statistically significant only at 9 months ($r = -0.32$, $P < 0.001$) but not at any other follow-up visit ($r = -0.11$ to -0.23, P = NS). At these latter follow-up visits, the correlation for UC was significantly higher ($P < 0.05$) than that for IT. Put another way, baseline SMC scores were significant predictors of subsequent HbA_{1c} for UC patients but not IT patients.

CONCLUSIONS — This article introduces a new index of diabetes SMC that combines measures of diabetes knowledge, treatment adherence, and health care interactions into a composite score characterizing the family's capacity to manage type 1 diabetes. This broader construct was well-correlated with HbA_{1c} levels, a finding that has been inconsistent in previous studies of relationships between self-management behaviors and diabetes control. The present findings

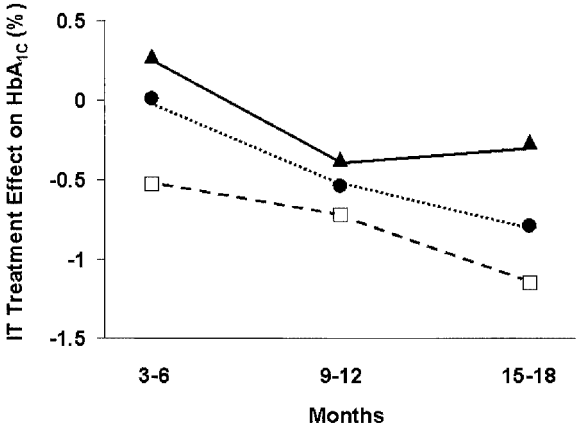

Figure 2—*Differences between mean HbA_{1c} levels of the IT and UC groups for patients at each SMC level over successive 6-month blocks of treatment. ▲, high SMC; ●, moderate SMC; □, low SMC.*

support the further use of this approach in subsequent research.

During an 18-month randomized trial of IT versus UC for youth with type 1 diabetes, we evaluated whether the metabolic outcomes of these regimens could be predicted by families' prevailing SMC levels. We hypothesized that greater benefit from IT would accrue to patients with moderate SMC because they would have pertinent prerequisite skills and room for glycemic improvement. However, the data showed that HbA_{1c} levels of low-SMC patients randomized to IT were indistinguishable statistically from those with moderate or high SMC. The IT effect on HbA_{1c} was larger for low-SMC patients than those with high or moderate SMC. This latter difference was partly attributable to the deterioration in HbA_{1c} among low-SMC patients in the UC group. Moderate- and high-SMC patients in the UC group experienced less pronounced increases in HbA_{1c}. Finally, correlations between baseline SMC and subsequent HbA_{1c} levels during treatment were significantly higher for UC than for IT at five of the six follow-up visits.

These results support two conclusions: *1*) SMC predicts the metabolic outcomes of UC but not of IT for youth with type 1 diabetes, and *2*) there is little empirical justification for denying access to IT for patients with low SMC. Indeed, our data suggest that patients with low SMC may derive the most glycemic improvement from IT. In contrast, high-SMC patients achieved similarly low levels of HbA_{1c} regardless of whether they received IT or UC. These findings may appear counterintuitive because more competent patients and families may often be seen as the best candidates for IT. One interpretation of these results may be that this UC regimen (e.g., quarterly clinic visits, two to three daily insulin injections, and three to four daily blood glucose tests) may actually place greater demands on patients and families than does an intensified regimen with more flexible treatment options and increased professional support. SMC may be more critical to the effectiveness of UC, whereas the added support and resources offered in IT may lessen the need for patients and families to be so heavily self-reliant.

One limitation of this study was that the participants may not represent the full spectrum of SMC. For example, some families with very high SMC levels may have declined participation because they either were receiving insulin pump therapy or were hoping to start it soon. Also, many patients and families who declined enrollment may have possessed even less SMC than those in the low-SMC group. However, several observations argue against this interpretation. First, our sample of 142 patients included 34 youth (24%) with $HbA_{1c} \geq 9.0\%$, ~1 SD above the mean for our diabetes clinic populations. Of these 34 patients, 13 (38%) were categorized as low SMC. Second, the absolute mean scores of the low-SMC patients on the DSMP (8) (62.2 of a possible 81 points) and DISC (7) (73.7 for youth, 98.5 for mothers, and 89.1 for fathers of a possible 174 points) clearly indicate suboptimal skills. Although we excluded participants with severe psychiatric disorders and unstable home situations from the study, the enrolled sample included many patients with inadequate treatment adherence, diabetes knowledge, and glycemic control. Nonetheless, the present study did not seek to establish the minimum SMC levels needed for successful IT. The present data indicate that patients and families with limited competence in diabetes self-management should not be denied access to IT with its attendant extra resources and support. In fact, the data suggest that these patients may realize the most glycemic benefit from this added support.

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