Self-Care Autonomy and Outcomes of Intensive Therapy or Usual Care in Youth with Type 1 Diabetes

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Objective   This article evaluated whether deviation from developmentally appropriate self-care autonomy moderated the effects of intensive therapy (IT) or usual care (UC) on glycosylated hemoglobin (HbA_{1C}) in 142 youths with diabetes.   **Methods**   Youths received an autonomy/maturity ratio (AMR) score at baseline that was a ratio of standardized scores on measures of self-care autonomy to standardized scores on measures of psychological maturity and were categorized by tertile split into low, moderate, and high AMR.   **Results**   Higher baseline AMR was associated with higher baseline HbA_{1C} for IT and UC. Baseline AMR scores predicted glycemic outcomes from UC; the high AMR tertile showed deteriorating glycemic control over time, whereas the low AMR tertile maintained better glycemic control. All three AMR groups derived equal glycemic benefit from IT.   **Conclusion**   Children with inordinate diabetes self-care autonomy may fare poorly in UC but these same children may realize less glycemic deterioration during IT.

Key words   adolescents; children; intensive therapy; type 1 diabetes.

The Diabetes Control and Complications Trial (DCCT) and the Epidemiology of Diabetes Interventions and Complications (EDIC) study proved that prolonged maintenance of excellent glycemic control through intensive therapy (IT) including extensive multidisciplinary support delayed the onset and slowed the progression of long-term complications of type 1 diabetes mellitus (T1DM) by some 50–75% (American Diabetes Association, 2002; Diabetes Control and Complications Trial Research Group, 1993, 1994) and that these benefits persisted (Diabetes Control and Complications Trial/EDIC Research Group, 2000; White et al., 2001). The 1,441 DCCT patients included 195 carefully selected adolescents (>13 years old at randomization), most of whom were young adults by the end of the study (Diabetes Control and Complications Trial Research Group, 1994). Although the benefits of IT may apply to adolescents and adults, IT is more difficult to implement in adolescents (Diabetes Control and Complications Trial Research Group, 1994, 1996). Also, extrapolation of results obtained from IT with adolescents to preadolescents with T1DM is unjustified. Thus, the relevance of the DCCT to the management of pediatric T1DM warrants additional confirmation. The American Diabetes Association (2002) has encouraged targeting near-normal glycosylated hemoglobin (HbA_{1C}) levels for all patients with T1DM unless there are overriding safety concerns. Elsewhere, researchers reported the results of an 18-month trial of IT versus usual care (UC) for youth with T1DM at two centers (White et al., 2002). In that trial, IT patients had mean HbA_{1C} during the treatment phase of the study of 7.8%, compared with 8.6% for UC patients, with no significant difference in severe hypoglycemia or weight gain between the groups.

In addition to more frequent insulin injections or use of an insulin pump, IT includes much more involvement of professionals from multiple disciplines with patients compared with UC and is more costly to deliver, especially in the pediatric age group (Diabetes Control and Complications Trial Research Group, 1993,

1994, 1996). As it was delivered in the DCCT, IT included monthly clinic visits with a diabetes nurse, weekly telephone calls from the nurse to assist in the adjustment of insulin, diet, or exercise, and free access to consultation from dietitians, psychologists, and other health professionals. The cost of delivering IT to adolescents in the DCCT was approximately four times that of standard treatment due primarily to the additional staff time required. Given the need for these additional resources, it is not possible to offer IT as delivered in the DCCT to every child with diabetes. Methods of reducing the cost or enhancing the outcomes of IT would be valuable, such as by reducing IT to its critical elements or offering IT to those most likely to derive benefit. Many youths, for example, are able to maintain excellent glycemic control during treatment with UC regimens. Hence, this article evaluates the prediction of glycemic benefit from IT or UC among patients in the above trial.

There is evidence that psychological and behavioral variables may be important moderators of the outcomes of intensified diabetes regimens. For example, Grey, Boland, Yu, Sullivan-Bolyai, and Tamborlane (1998) reported that adolescents' quality of life during IT was associated with a variety of psychological variables, including treatment satisfaction, coping styles, depressive symptoms, and diabetes self-efficacy. Analyzing data from the randomized trial on which this article is also based, Wysocki, Harris, Wilkinson, Mauras, and White (2003) reported that youths' diabetes self-management competence, as assessed by a composite of scores on measures of treatment adherence, diabetes knowledge, and quality of health care interactions, moderated the effects of IT and UC regimens on glycemic control. Youths with low self-management competence derived greater relative and absolute glycemic benefit from IT than did those with moderate or high self-management competence.

Among other variables that might be expected to influence a family's capacity to successfully implement a complex regimen such as IT for diabetes is the degree to which the child's responsibility for diabetes management deviates from that child's developmental capacity for those responsibilities. Several studies suggest that transfer of responsibility from parents to adolescents may be influenced heavily by considerations other than the child's maturity and readiness for responsibility such as age and physical maturity (Allen, Tennen, McGrade, Affleck, & Ratzan, 1983; Ingersoll, Orr, Herrold, & Golden, 1986; La Greca, Follansbee, & Skyler, 1990; Palmer et al., 2004). Others have found that disagreement between parents and adolescents about who is responsible for diabetes tasks was associated with poor diabetic control (Anderson, Auslander, Jung, Miller, & Santiago, 1990). Youths with levels of diabetes management responsibility that exceed their knowledge, problem solving skills, and personal maturity may have particular difficulty negotiating the demands of a complex IT regimen for diabetes. Specific mechanisms that could mediate these effects may include the possibility that youths with excessive self-management autonomy may be prone to inadequate treatment adherence, deficient diabetes problem solving skills, difficulty seeking guidance from adults regarding diabetes management, and diminished self-efficacy regarding proactive self-regulation of the regimen.

Wysocki, Taylor, et al. (1996a) reported that youths with T1DM and inordinate self-care autonomy relative to their psychological maturity were at greater risk of poor treatment adherence, worse diabetic control, and more hospitalizations than those with constrained or appropriate levels of responsibility. Youths with developmentally excessive autonomy appeared to assume greater responsibility for diabetes self-management than was warranted by their cognitive maturity while also receiving less monitoring and guidance than needed from their adult caregivers. That cross-sectional study introduced the autonomy/maturity ratio (AMR), an index of the deviation of a child's diabetes self-care autonomy from developmentally appropriate levels. The AMR is a ratio of mean composite standardized scores on two measures of self-care autonomy (Anderson et al., 1990; Wysocki, Meinhold, et al., 1996) to mean composite standardized scores on measures of cognitive (Das & Naglieri, 1997), social (Schultz, Yeates, & Selman, 1989), and academic (Jastak & Wilkinson, 1991) maturity. A tertile split of AMR scores categorized youths as low, moderate, or high self-care autonomy relative to their measured levels of psychological maturity.

This article evaluates whether patients' baseline AMR scores moderated the metabolic outcomes of IT or UC regimens. Our central hypothesis was that patients with AMR scores in the moderate tertile would derive greater benefit (or prevention of deterioration) from IT than would those with scores in the low or high tertiles. The rationale for this hypothesis was that patients with developmentally appropriate responsibility for diabetes management would be better equipped to achieve improvement in metabolic control with the added multidisciplinary support and resources entailed in IT. Researchers further hypothesized that patients with high AMR scores would show poor and/or deteriorating glycemic control when treated with UC.

Methods

Recruitment of Participants

Families were recruited and received T1DM care during the trial either at St. Louis Children's Hospital at Washington University in St. Louis, MO or Nemours Children's Clinic in Jacksonville, FL. Before a clinic appointment, families of potentially eligible youths received an introductory letter from the child's attending endocrinologist. Soon thereafter, the trial coordinator telephoned parents to verify the youth's eligibility, answer questions about the study, and offer to meet with the family at the clinic visit to explain the project in detail. The research protocol was reviewed and approved by institutional review boards at both performance sites. Informed consent was obtained from parents and assent from youths before the collection of any study data by using institutionally approved forms.

To be eligible, youths must have been at least 6, but not yet 16, years old at enrollment, diagnosed with T1DM for at least 2 years (or for at least 1 year with a negligible stimulated c-peptide level measured at the Washington University General Clinical Research Center), free of other chronic medical conditions except well-controlled Hashimoto thyroiditis or well-controlled asthma and with normal cognitive and academic function for age. Youths with T1DM were required to reside in a family situation, to anticipate remaining in that home during study participation, to have telephone service, and to plan on continuing to receive diabetes therapy at the enrolling center throughout the study. Participating 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. The youth with T1DM could not have been a psychiatric inpatient in the prior 6 months. Biological and stepparents living with the patient were expected to participate; other adults residing in the home participated if they chose to do so.

A total of 446 potentially eligible families were contacted about the study at the two sites. Of these, 147 families (33%) enrolled and completed baseline evaluations. A sample of 35 eligible families of the 299 families who declined enrollment signed authorization forms permitting the collection of basic demographic information and their reasons for declining participation. Reasons for refusing participation included travel or scheduling problems, hesitance about the regimen burden, and reluctance to defer insulin pump therapy if randomized to UC. There were no statistically significant differences between these "decliners" and those who enrolled for child age, gender, race, HbA_{1C}, family composition, or family socioeconomic status. Although it would have been desirable to obtain such data from all families who declined participation, regulatory requirements prevented doing so except for patients whose parents signed an explicit authorization to provide the researchers with this information. Most families who declined enrollment did so when contacted by telephone after a recruitment encounter in the clinic, rather than during the clinic encounter. Thus, it was difficult to obtain these signed authorizations from most families who declined enrollment. Soon after randomization, five families withdrew from the study (two IT and three UC), leaving 142 families who contributed data for this report.

Experimental Design and Treatment Regimens

Youth were randomized to 18 months of treatment with UC or IT. Randomization was stratified by patients' age (<10, 10–12, >12 years old) and HbA_{1C} (<7.5, 7.5–9.0, >9.0%) to promote equivalence of the groups. Study measures were collected at baseline before randomization, at quarterly evaluations and at comprehensive evaluations scheduled 9 and 18 months later. Reports of HbA_{1c}, severe hypoglycemia, hospitalizations, emergency room care, weight gain, and treatment fidelity were sent twice annually to an advisory panel of three pediatric endocrinologists who were not affiliated with either of the study center. Components of the two regimens are summarized below.

UC

UC patients ($n = 70$) were managed with the prevailing T1DM regimen at the two sites during the study (1997 through 2001). Glycemic targets were $HbA_{1C} \leq 8.0\%$; average premeal blood glucose between 70 and 140 mg/dL; average postprandial blood glucose <180 mg/dL; 3 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, systematic diabetes education (Task Force to Revise the National Standards, 1995), and annual clinic visits with a dietitian and a psychologist.

IT

Participants randomized to IT ($n = 72$) were offered as much multidisciplinary support as needed to approach targets of $HbA_{1C} < 6.5\%$; average premeal blood glucose between 70 and 120 mg/dL; average postprandial blood glucose <150 mg/dL; 3 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 a.m. blood glucose tests; weekly telephone contact initiated by a diabetes nurse; services

as needed from a registered dietitian and a psychologist without charge; monthly visits with the diabetes nurse and quarterly visits with a pediatric endocrinologist; advanced diabetes education; and the opportunity to attend a monthly IT support group. During the study, compared with UC patients, IT patients received six times as much contact with diabetes nurses and three times as much contact with dietitians and psychologists.

Measures

Measures collected before, during, and after the treatment phase of the study, included indices of treatment outcome and possible predictors and moderators of treatment outcome. Only measures analyzed for this article are described here.

Parents reported demographic information and the child's medical history. This included information needed for the calculation of the Hollingshead Four-Factor Index of social status (Hollingshead, 1975) as well as other descriptive and categorical information.

Glycosylated hemoglobin, the primary measure of recent glycemic control, was measured at each quarterly clinic visit as HbA_{1c} by using the DCA2000+ system (Miles Laboratories), which employs a specific monoclonal antibody and a turbidimetric assay. Patients tested blood glucose daily by using a glucose meter with memory and were asked to bring the meters to each visit for computer download and analysis by clinicians. Parents maintained a severe hypoglycemia diary to report the occurrence, management, and outcome of hypoglycemic events that met any of these criteria, which could co-occur within a given episode: (a) occurrence of a seizure or loss of consciousness; (b) assistance of another person was required to interrupt the episode; (c) the episode required administration of Glucagon or administration of IV dextrose under the direction of a health professional; or (d) child was treated by an emergency medical squad or taken to an emergency room. Parents were asked to report these events to the clinic as soon as possible after the episode. Other medical variables recorded at each quarterly clinic visit were hospitalizations and emergency room admissions (reported by parents and verified by nurses), and the child's height, weight, body mass index, linear growth velocity, and Tanner stage of pubertal development.

Calculation of AMR

The administration of the tests and questionnaires required for the calculation of the AMR required about 20–30 min for parents and about 75 min for younger children and up to 120 min for adolescents. Self-care autonomy was defined as the degree to which diabetes responsibilities resided with the child rather than a parent. Self-care autonomy was measured by using two parent-completed questionnaires: the Diabetes Independence Survey (Wysocki, Meinhold, et al., 1996), a measure of youth's mastery of 38 diabetes self-care skills and the Diabetes Family Responsibility Questionnaire (Anderson et al., 1990), a measure of parent and child sharing of 17 diabetes responsibilities. Alpha coefficients based on data obtained in this study were .93 for the Diabetes Independence Survey and .88 for the Diabetes Family Responsibility Questionnaire. Based on data obtained on these measures from several study samples, raw scores on these scales were transformed into age-adjusted standard scores with a mean of 100 and standard deviation of 15. The two standard scores were then averaged to yield a composite self-care autonomy score for each child. Pearson correlation between these two measures was $r = .39$ ($p < .001$), suggesting that combining the two measures into a composite score was justifiable. Similarly, a composite index of each child's psychological maturity was derived based on the mean of age-adjusted standard scores for several well-validated tests of general intelligence [Das-Naglieri cognitive assessment system (CAS); Das & Naglieri, 1997], social cognition [interpersonal negotiation strategies interview (INS); Schultz et al., 1989]; and academic achievement [wide-range achievement test-revised (WRAT-R); Jastak & Wilkinson, 1991]. Mean age-adjusted standard scores on these instruments indicate that the sample performed close to normative levels on all three (CAS M = 108.1, SD = 12.2; WRAT-R M = 102.3, SD = 11.0; and INS M = 106.5, SD = 13.4). Pearson correlations among these measures ranged from .38 to .51, justifying the formation of a composite index combining the three scores. The ratio of the diabetes self-care autonomy composite score to the psychological maturity composite score yielded the AMR for each child. The calculation of the AMR assumed equal weighting of the skills that comprised it. Based on a tertile split of the distribution of AMR scores, youth were categorized as demonstrating either low (lowest tertile), moderate (middle tertile), or high self-care autonomy (highest tertile) relative to their measured psychological maturity. The three AMR groups did not differ significantly in scores on the CAS, WRAT-R, or INS. Although the preservation of the AMR as a continuous variable has merit, the decision to treat it as a categorical variable was based on the objective of presenting and interpreting the main study findings as clearly and succinctly as possible.

Statistical Analyses

A 2 × 3 × 7 repeated measures analysis of variance was conducted with treatment regimen (UC or IT) and AMR

group (low, moderate, or high) as the between-subjects factors and HbA$_{1C}$ levels obtained at baseline and each of the six quarterly clinic visits as the dependent variable. Missing HbA$_{1C}$ values, (48 of 994 scheduled tests; 4.8%), were replaced by using a generalized least squares estimation procedure. Significant between group or group by time interaction effects were followed by the computation of appropriate post-hoc analyses to specify the sources of statistically significant effects. Multiple regression analyses treating AMR scores as a continuous variable yielded results that are virtually identical to those reported below.

Secondary analyses performed following the above analysis consisted of efforts to determine if the treatment regimens differentially affected youths' AMR scores over time and to determine if the numerator of the AMR score (composite score for autonomy) yielded moderating effects on glycemic outcomes of the IT and UC regimens that were similar to those of the AMR score itself.

Results
Sampling Plan

In a previous article (White et al., 2001), researchers described the demographic characteristics of the sample in detail and reported that the IT and UC groups were similar in patients' age (M = 11.3 years), race (87% Caucasian, 11% African American, 2% other), socioeconomic status (mean Hollingshead Index = 43.3; range = 13–66; maximum possible range = 9–66), family composition (79% two-parent), and baseline HbA$_{1C}$ concentrations (M = 8.3%). The only demographic difference among the three AMR tertiles was that, as expected, youth in the low tertile were slightly younger (M age = 10.6 years) than those in the high tertile (M age = 11.9 years). Thus, as in our earlier study (Wysocki, Taylor, et al., 1996), older youth were slightly more likely to have higher levels of self-care autonomy relative to their psychological maturity when compared with younger children.

Measurement Properties of the Autonomy to Maturity Ratio

With the IT and UC samples combined, mean baseline HbA$_{1C}$ (±1 SD) for patients with AMR scores in the low tertile was 7.9 ± 1.0%, which was significantly lower than the mean values of 8.5 ± 1.1% for the moderate tertile and 8.6 ± 1.2% for the high tertile, $F(2, 140)$ = 4.64, p < .01. At baseline, AMR scores correlated significantly with HbA$_{1C}$ (r = .27, p < .01) and this association

remained significant for the UC group at four of the subsequent six HbA$_{1C}$ determinations during the study. These significant associations between the AMR score and HbA$_{1C}$ levels support the predictive validity of this index. Test–retest reliability of the AMR was supported by a significant correlation between the baseline AMR score and the values obtained at 9-month (r = .50, p < .0001) and 18-month (r = .38, p < .001) intervals among UC patients.

Effects of Treatment Regimen and AMR Tertile on Glycemic Control

Figure 1 displays mean (±1 SEM) HbA$_{1C}$ at baseline and throughout the 18 months of treatment for IT and UC patients in the three AMR groups. Repeated measures analysis of variance revealed a significant main effect for regimen, $F(6, 131)$ = 8.57, p < .001, and a significant
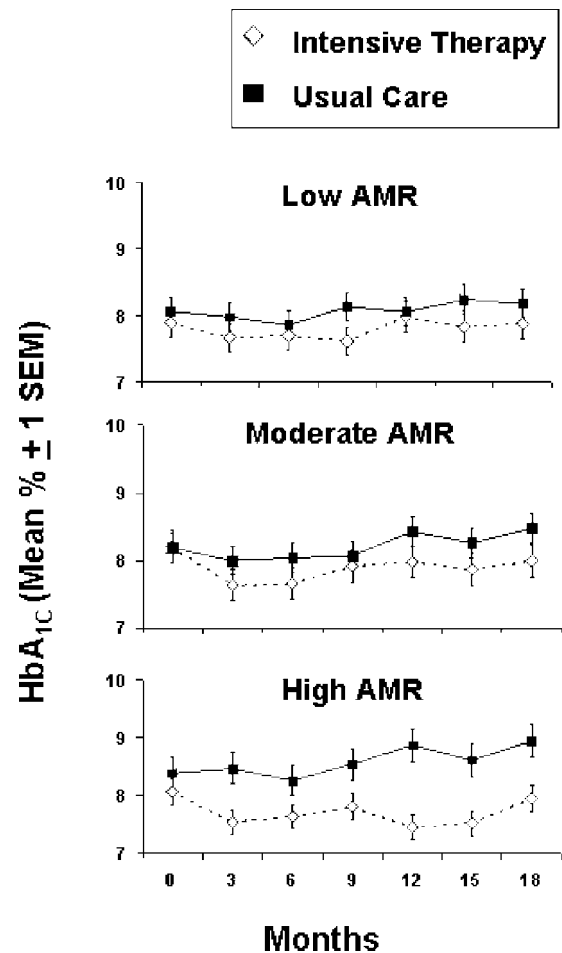

Figure 1. Mean glycosylated hemoglobin (HbA$_{1C}$) levels (±1 SEM) at baseline and throughout 18 months of treatment with the intensive therapy (IT) and usual care (UC) regimens for patients with autonomy/maturity ratio (AMR) scores in the low (top graph), moderate (middle graph), and high (bottom graph) tertiles.

regimen by time interaction effect, $F(6, 131) = 3.71$, $p <$ .002, with both effects indicating lower HbA_{1C} levels for IT than for UC. Thus, IT improved glycemic control compared with UC. Further, there were significant interaction effects for regimen by AMR group, $F(2, 138) = 4.03$, $p < .01$, and for regimen by AMR group by time, $F(12, 216) = 2.96$, $p < .02$. Post-hoc analyses indicated no differential effects of IT and UC on HbA_{1C} levels occurred for patients with low AMR, but, for patients with high AMR, IT yielded significantly lower HbA_{1C} than UC and these effects increased with increasing duration of treatment. Figure 1 also reveals that, in response to IT, the three AMR groups achieved similar absolute HbA_{1C} levels over the 18 months of treatment. Mean (± 1 SD) HbA_{1C} during IT treatment was 7.8 ± 0.8, 7.8 ± 0.7, and 7.9 ± 0.9%, respectively, for the low, moderate, and high AMR groups ($p = ns$). Thus, the mean absolute HbA_{1C} levels achieved by the three AMR groups during IT were indistinguishable. In contrast, significant differences were found among AMR groups receiving the UC regimen, $F(2, 140) = 5.34$, $p < .01$. At four of the six quarterly clinic visits for UC patients, those in the high AMR range had significantly higher HbA_{1C} than either one or both of the low and moderate AMR groups.

In addition to analyses of effects on absolute HbA_{1C} levels, as shown in Fig. 1, relative changes in glycemic control during the study were also examined. When examining IT patients only, the difference between HbA_{1C} obtained at baseline and the mean HbA_{1C} value during treatment differed among those in the low (–.17%), moderate (–.47%), and high (–.79%) AMR tertiles. Analysis of variance of these HbA_{1C} change scores for individual IT patients, treating AMR tertile as the between-subjects factor yielded a significant main effect for groups, $F(2, 138) = 5.31$, $p < .001$. Post-hoc analyses showed that patients in the high tertile realized significantly more glycemic improvement than those in either of the other two tertiles and that the low and moderate groups did not differ significantly from one another. Thus, glycemic benefits of IT were dependent upon the patient's AMR tertile; those in the low AMR tertile derived significantly less benefit than those in the high AMR tertile.

Corresponding analyses limited to UC patients indicated mean increases in HbA_{1C} during the 18 months of treatment of .08% for low AMR, .18% for moderate AMR, and .22% for high AMR, but the main effect for groups was not significant, $F(2, 138) = 1.69$, $p < .9$.

Because the AMR is a ratio, it is possible that the observed effects may be attributable to one component of the ratio alone. Consequently, the above analyses were repeated by using tertile scores as obtained above for the autonomy and maturity composite score. The Group X Time–Autonomy interaction effect, $F(1, 139) = 0.83$, $p = ns$, and the Group X Time–Maturity interaction effect, $F(1, 139) = 1.38$, $p = ns$, both failed to achieve statistical significance.

Additionally, because children in the three AMR tertiles differed significantly in age, it is possible that resulting associations could be attributable to age or other indices of maturity rather than the AMR scores. In an effort to clarify this question, parallel analyses were completed with age group and Tanner stage of pubertal development, rather than AMR tertiles, as between-subject variables. None of these additional analyses yielded any statistically significant main effects for age or Tanner stage or any statistically significant interaction effects involving either age or Tanner stage with treatment regimen or time.

Effects of Treatment Regimen on AMR Scores

Effects of treatment regimen on AMR scores were evaluated by using a two (regimen) by three (AMR scores at 0, 9 and 18 months) repeated measures ANOVA. Neither the main effect for group, $F(1, 139) = 1.38$, $p = ns$, nor time, $F(1, 139) = 0.93$, $p = ns$, achieved statistical significance. The group by time interaction effect fell just short of statistical significance, $F(2, 138) = 2.41$, $p < .10$, with AMR scores decreasing slightly for the IT group and increasing slightly for the UC group from baseline to 18 months.

Discussion

This article illustrates the strengths of longitudinal research designs in examining the effects of psychological variables on the relative outcomes of two medical regimens. In addition to verifying that IT is feasible, safe, and effective in a pediatric sample of T1DM patients, the study yielded interesting and valuable information about the prediction of therapeutic benefit from these regimens.

The study failed to support the primary hypothesis that was tested, that is, that youths with AMR scores in the moderate tertile would demonstrate greater benefit from IT than those in the high and low AMR tertiles. Instead, youths in the high AMR tertile who were randomized to IT realized significantly less deterioration in glycemic control relative to the low and moderate AMR tertiles and compared with their counterparts in the UC group. These findings suggest that youths who have had inordinate self-care autonomy may derive the most

benefit from the added professional support and encouragement entailed in the IT regimen that was evaluated in this trial.

This article extends previous research on the correlates of deviation from developmentally appropriate self-care autonomy by examining whether an index of this construct predicted outcomes of IT and UC regimens for T1DM. Youths' baseline scores on the AMR were used to estimate their deviation from developmentally appropriate diabetes self-care autonomy. During an 18-month trial of IT versus UC for youth with T1DM, researchers evaluated whether metabolic outcomes of these regimens could be predicted by youths' scores on this index. Researchers hypothesized that IT patients with AMR scores in the moderate range would derive more benefit, because they would presumably have stronger prerequisite skills and developmentally appropriate adult supervision for adapting to this more demanding regimen. Although our findings were not consistent with this hypothesis, our data nonetheless provide valuable information regarding the selection of candidates for IT and its attendant multidisciplinary support. Baseline mean HbA_{1C} of patients with high and moderate AMR were significantly higher than the levels for patients with low AMR. Of both absolute and relative glycemic change, patients with high AMR realized equal or greater benefit from IT compared with those with low or moderate AMR. Absolute levels of glycemic control of patients with high AMR at baseline who were randomized to IT were indistinguishable from those with low or moderate AMR throughout the study. Improvement in glycemic control relative to each patient's baseline HbA_{1C} suggested that the magnitude of the relative IT treatment effect on HbA_{1C} was larger for high AMR patients compared with those in the other tertiles. The prevention of glycemic deterioration achieved by IT patients in the high AMR tertile may have been partly attributable to deterioration in HbA_{1C} among their counterparts in the UC group. Low and moderate AMR patients in the UC group experienced less pronounced increases in HbA_{1C}. Put another way, IT appeared to erase the apparent glycemic disadvantages conferred to those with high AMR. IT may help youth with high AMR achieve improved glycemic control comparable with that realized by those with moderate and low AMR.

Several possible interpretations of these findings merit discussion. It is possible that the improvements in glycemic control of high AMR patients represent regression toward the mean because their baseline HbA_{1C} levels were higher than the other groups. Similarly, the significant correlation between HbA_{1C} and AMR scores

may simply have persisted throughout the 18-month trial. These explanations of the study findings as statistical artifacts fail to account for UC patients showed no regression to the mean in HbA_{1C} levels. The observation that high AMR patients in IT realized substantial glycemic benefits from that regimen, whereas high AMR patients in UC instead suffered deterioration in glycemic control also argues against these interpretations.

Despite the components of the AMR ratio were all adjusted for age, the three AMR tertiles differed significantly in age, with high AMR youths slightly older ($M = 11.6$ years) than low AMR youths ($M = 10.8$ years). Thus, it is possible that the associations reported here for AMR scores were artifacts of these associations. Additional analyses evaluated these possibilities. These analyses showed that neither age quartile nor Tanner stage proved to be significant determinants of response to either IT or UC, either as main effects or interaction effects. Thus, glycemic benefit from the IT and UC regimens was independent of either the child's age or level of pubertal development at enrollment.

The specificity of the AMR as a moderator of glycemic outcomes was supported by analyses showing that the numerator of the AMR (composite scores for autonomy and maturity) did not have similar effects on HbA_{1C} as were obtained in analyses treating the AMR score as a moderator. This implies that it is the relationship between autonomy and maturity that is important to consider clinically, rather than either autonomy or maturity alone.

In a previous report based on this same trial (Wysocki et al., 2003), researchers showed that youths with low self-management competence (a composite score incorporating measures of treatment adherence, diabetes knowledge, and quality of health care interactions) at baseline were more likely to derive glycemic benefit from IT compared with those with moderate or high self-management competence, yet low self-management competence was associated with deterioration in glycemic control during treatment with UC. This article extends that finding by showing that the rate at which children assume diabetes management responsibilities relative to their maturity levels is also a significant predictor of glycemic outcomes of these regimens. The present findings complement those reported in the earlier article in showing that patients with suboptimal pretreatment status on several relevant clinical characteristics derived substantial benefit from IT. Specification of possible mechanisms of these findings remains purely speculative. The extensive support, encouragement,

and advanced, sophisticated medical advice offered by the diabetes nurses are likely to be crucial. Relative to the UC group, IT patients and their families experienced almost six times more contacts (clinic visits, phone calls) with the diabetes nurses. The role of dietitians and psychologists is also likely to be of considerable importance. IT patients and families experienced three times the frequency of contacts with these professionals as did UC patients during the trial. Repeated measures ANOVA failed to substantiate differential change in AMR scores between the IT and UC groups during the study, although the sample size may not have provided sufficient statistical power to detect the pertinent group by time interaction effect.

The results presented here support three conclusions:

1. The degree to which youths assume self-care autonomy that matches their psychological maturity moderated metabolic outcomes of UC but not of IT. During UC treatment, youth with high AMR fared poorly over time; during IT, HbA_{1C} levels of the three AMR tertiles were indistinguishable. However, the finding that low AMR patients achieved similar glycemic control on both the IT and UC regimens suggests that such patients may not require the added support offered in IT.
2. There is little empirical justification for denying access to IT for patients with excessive levels of self-care autonomy. Patients who are judged to have inordinate responsibility for diabetes management might often be seen by clinicians as being poor candidates for advances in medical care that may carry greater psychological demands than standard care. Indeed, our data suggest that patients with high AMR scores may derive the most improvement in HbA_{1C} from IT relative to their baseline levels. In contrast, low AMR patients in this trial achieved similar, very good glycemic control whether they were treated by using an IT or UC regimen.
3. The temporal stability and predictive validity of the AMR index received empirical support, extending the findings of a prior cross-sectional study (Wysocki, Taylor, et al., 1996). The index was correlated significantly with HbA_{1C} at baseline and during the continuation of UC, supporting the further use of this measure as a research tool.

The favorable results of IT achieved with the high AMR group may appear counterintuitive because heavy involvement of parents in diabetes management may often be seen as indicative of good candidacy for IT. One interpretation of these results may be that a UC regimen such as that in this study (e.g., quarterly clinic visits, two to three daily insulin injections, three to four daily blood glucose tests) may place greater demands on patients and families than does an intensified regimen with more flexibility and much more professional support. Maintenance of developmentally appropriate self-care autonomy 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.

Since calculation of the AMR was based on the administration of a test battery by a psychologist requiring 75–120 min per patient, this is unlikely to be feasible in most clinical settings. Future research is needed to validate methods of acquiring similar information more efficiently, such as by reducing the number of measures incorporated into the AMR or by developing one or more questionnaires that obtain comparable data from parents or clinicians. Although the present results may not be immediately or readily translated into clinical practice, the findings are valuable in that they question the merits of the common approach of limiting access to new, intensive, or technically advanced treatments to only "model" patients and families. The present findings send an egalitarian message about intensive diabetes management: that patients who might not appear to be the best candidates for this approach derived comparable glycemic benefits to those who might be considered "better" candidates. The development and validation of a briefer and more practical version of the AMR would be valuable.

One limitation of this study is that the youths may not represent the full spectrum of deviation from developmentally appropriate self-care autonomy. For example, some patients and families with extreme AMR scores may have selectively declined study participation. However, there are reasons to believe that such concerns are erroneous. First, the distribution of AMR scores for this sample was virtually indistinguishable from that reported in an earlier cross-sectional study that validated that index (Wysocki, Meinhold, et al., 1996). Second, although researchers excluded participants with severe psychiatric disorders and unstable home situations from this study, the enrolled sample included many patients with inadequate treatment adherence, diabetes knowledge, and glycemic control. Nonetheless, this study did not seek to establish the minimum or maximum AMR scores that are necessary for successful treatment with IT.

The respective regimens did not yield differential effects on change in AMR scores during the 18-month study, and so the glycemic benefits of IT cannot be

attributed to such effects. Change in the AMR score was minimal during the study for children on both regimens and this lack of variability may have hindered demonstration of such effects. Further, neither the IT nor the UC regimen systematically targeted change in self-care autonomy. The specification of the mechanisms that mediate therapeutic benefits such as those reported here would represent valuable contributions in future studies.

The results presented here should be interpreted cautiously and responsibly before implementing them in clinical contexts. The findings are limited to the type of IT regimen evaluated in this trial, one that incorporated very extensive multidisciplinary support and guidance to patients and parents. One should not conclude that the present findings apply also to intensified regimens such as insulin pump therapy that do not incorporate comparable levels of multidisciplinary care and support. Also, many patients and families may wish to initiate IT regimens in an effort to provide more flexibility in daily living such as enabling day-to-day variation in mealtimes or amounts eaten at each meal. This study does not address the prediction of benefit from IT when enhanced flexibility of lifestyle is the goal of initiating it.

The present data indicate that patients with responsibility for diabetes self-care that exceeds their levels of developmental and cognitive maturity should not be denied access to IT with its attendant extra resources and support. The data suggest that these patients may realize the most glycemic benefit from this added support.

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