Insulin Pump Therapy and Health-Related Quality of Life in Children and Adolescents with Type 1 Diabetes

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Objectives To compare the health-related quality of life (HRQOL) of youths on injection regimens to those prescribed insulin pump therapy and examine factors related to HRQOL in youths with type 1 diabetes.

Methods An ethnically diverse group of youths (n = 160, ages 5–17 years) with type 1 diabetes and their caretakers completed family, parent, and child adjustment measures, as well as measures of generic- and disease-specific HRQOL. Metabolic control and regimen information were assessed through medical records.

Results HRQOL was unrelated to regimen prescription. Child, family, and parent adjustment variables were significantly related to HRQOL, whereas other demographic and clinical variables were relatively less important.

Conclusions Present findings indicate that insulin pump therapy does not have negative implications for HRQOL. They also suggest that interventions aiming to improve HRQOL in this population should target child, parent, and family adjustment and not focus solely on disease-related outcomes.

Key words health-related quality of life; insulin pump therapy; type 1 diabetes.

Type 1 diabetes is the most prevalent metabolic illness of children, affecting approximately 151,000 children and adolescents in the United States alone (NIDDK, 2002). Recently, intensive therapies that include multiple daily injections (MDI) or insulin pump therapy have been prescribed with the goal of maintaining nearly normal blood glucose levels to avoid health complications. MDI insulin regimens require three or more injections. These injections are typically made up of a combination of long-acting insulin such as Glargine or NPH with multiple doses of rapid-acting insulin either Lispro or Aspart. Conventional regimens, on the other hand, require only two or fewer injections. Along with giving more injections, intensification of treatment means that youths must monitor their blood glucose more frequently and estimate their carbohydrate intake before insulin injections. The focus on achieving near normal blood glucose levels may require more skill, time, and responsibility for youths with diabetes and also lead to more family involvement with the child’s self-care regimen.

Pump therapy is one of the most technologically advanced methods of achieving near normal blood glucose levels, and there are at least four advantages to using the pump to intensify treatment (Bode et al., 2002). First, insulin is absorbed in a more stable manner which may lead to improved glycemic control over MDI (Weissberg-Benchell et al., 2003). Second, studies have shown a decreased risk of the “dawn phenomenon,” which is a common rise in blood glucose before breakfast and also better control throughout the night (Kaufman et al., 1999; Pickup & Keen, 2002). Third, the insulin pump gives patients more flexibility in the timing of their meals. Patients on the pump can adjust for snacks and meals, as well as for exercise and physical exertion. Finally, studies have shown that the pump reduces the occurrence of serious hypoglycemic episodes (Boland et al., 1999; Maniatis et al., 2001). To date, however, few studies have addressed how the adjustment to pump therapy affects the health-related quality of life (HRQOL) of children and adolescents.

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doi:10.1093/jpepsy/jsj088
Advance Access publication December 1, 2005
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A recent meta-analysis of the metabolic and psychosocial impact of pump therapy concluded that there is a paucity of research on the potential psychosocial impact of this regimen (Weissberg-Benchell et al., 2003). Studies looking at adults have found that, in general, intensifying treatment either maintains (The DCCT Research Group, 1996) or improves the HRQOL of adults with diabetes (Weinger & Jacobson, 2001). Only two recent studies have examined how pump therapy affects children and adolescents. The first study by Boland et al. (1999) found improved HbA1c and fewer hypoglycemic episodes over time for adolescents, 12–20 years old, on the pump compared to MDI. Both participants who had chosen MDI and those who chose pump therapy had significant improvements in QOL, as measured by the diabetes quality of life: youth inventory (DQOLY). However, no significant differences in diabetes-specific QOL were found between the two groups. The results of the study also indicated better coping in adolescents on the pump compared to those on MDI. The second study (Kaufman et al., 1999) showed a significant increase in scores on tests of knowledge, adherence, responsibility, integration, family guidance/control, and HRQOL after initiation of pump therapy in a group of 83 adolescents. The investigators observed that 90% of those who initiated pump therapy in their study chose to continue on the pump. They did not, however, observe differences between the HRQOL of adolescents on pump therapy and those on MDI. These studies suggest that pump therapy may improve HRQOL when compared to conventional therapy but not necessarily when compared to MDI. However, limitations of these studies, as well as the paucity of studies in this area, indicate a need for more research. This is important because the number of people in the US using insulin pump therapy has increased from 15,000 in 1993 to 162,000 in 2001 (Bode et al., 2002). Also, due to concerns about hypoglycemia in young children, insulin pump therapy was originally implemented only in adolescents. However, pump therapy is now frequently being used safely and effectively in toddlers and preschoolers (Litton et al., 2002).

It is important to note that most current HRQOL literature in the area of diabetes has not considered participants under the age of 11 or data on generic HRQOL domains, and few studies include a diverse group of ethnic minority children. Presently, the literature measures HRQOL in this population almost exclusively using Ingersoll and Marrero’s (1991) DQOLY measure (Delamater, 2000). Like many HRQOL measures for youths, this measure is adapted from a HRQOL measure developed for adults [The Diabetes Control and Complications Trial Research Group (DCCT), 1988; Ingersoll & Marrero, 1991]. Although the DQOLY has demonstrated good psychometric properties, it is not appropriate for youths under the age of 11 and was not designed to measure generic HRQOL. It does not include information about functional status, intensity of physical symptoms, or psychological functioning.

Findings from studies that have used the DQOLY to look at the HRQOL of adolescents with type 1 diabetes indicate the following about diabetes-specific QOL in children. First, studies have consistently found that girls endorse more diabetes-related worries, less satisfaction, and have poorer perceptions of their own health than boys (Eiser et al., 1992; Grey et al., 1998; Hvidore Study Group on Childhood Diabetes, 2001; Ingersoll & Marrero, 1991). Second, studies are mixed concerning the relationship between glycemic control in children and QOL. Some studies have found no relationship between glycemic control, as measured by HbA1c, and diabetes-specific QOL (Grey et al., 1998; Hoare et al., 2000; Ingersoll & Marrero, 1991). However, a few studies have indicated that better glycemic control is related to better QOL outcomes (Guttmann-Bauman et al., 1998; Hvidore Study Group on Childhood Diabetes, 2001).

Some research on HRQOL in youths with type 1 diabetes also suggests that child adjustment and family functioning are significantly related to diabetes-specific QOL. A study by Grey et al. (1998) found that adolescents who were depressed were more likely to report poorer QOL. The same study also found that adolescents with warm and caring families were more satisfied with their diabetes-specific QOL. Further, adolescents with families who provided more diabetes-specific guidance had improved HbA1c and were less impacted by the disease. Similarly, Laffel et al. (2003) found that child report of diabetes-specific family conflict significantly predicted HRQOL. In fact, in one study, youths with type 1 diabetes ranked “family” as the second most important domain related to HRQOL (Wagner et al., 2004).

Recently, a newer modular approach to measuring HRQOL has been established. The PedsQL 4.0 Generic Core Scales (Varni et al., 2001) and the PedsQL 3.0 Type 1 Diabetes Module (Varni et al., 2003) were designed to be used together in an assessment of both generic- and disease-specific QOL. Many authors have focused on the benefits of measuring both generic- and disease-specific QOL. Delamater, 2000; Parkerson et al., 1993; Varni et al., 2005). Generic measures allow for comparisons to occur across different disease populations and healthy groups, whereas disease-specific measures
are more sensitive to changes within a clinical group. A modular approach allows for the most comprehensive evaluation of HRQOL. The PedsQL modular instrument is also unique in that it is the only measure of its kind to be developed specifically for a wide age range (2–18 years old) with both self-report and parent proxy report. Psychometric findings indicate that the PedsQL generic and diabetes modules are reliable and valid for use as outcome measures in diabetes clinical trials and research (Varni et al., 2003). Already, this instrument has been used to compare the HRQOL of youths with diabetes to healthy peers (Laffel et al., 2003; Varni et al., 2003).

Because insulin pump therapy is increasingly used as part of routine diabetes care (Kaufman et al., 1999), it is important to examine how children and adolescents are affected by this intensive regimen. Given the aforementioned limitations in the literature, the primary aim of this study was to investigate HRQOL in children and adolescents with type 1 diabetes using the newer modular approach to HRQOL measurement. Due to the health benefits and flexibility afforded by pump therapy, it was expected that pump therapy would be related to better generic- and disease-specific HRQOL compared to injection regimens.

A second aim was to examine the relationships between child and parent adjustment, and family functioning variables and the HRQOL of youths with type 1 diabetes. Child report of depressive symptoms and family conflict have been associated with HRQOL in two previous studies (Grey et al., 1998; Laffel et al., 2003). Also, Parkerson et al. (1993) have shown that, at least in adults, nondiabetic factors can be more important predictors of HRQOL than clinical variables. In this study, it was hypothesized that nonclinical factors, including child distress, child behavior problems, parent distress, and family maladjustment, would be related to the overall generic- and disease-specific HRQOL of youths.

Method

Participants

Participants included 160 children and adolescents (54% female) with type 1 diabetes mellitus and their mother (85%), father (14%), or foster parent (1%). Youths ranged from ages 5–17 years with a mean age of 10.86 years (SD = 3.65). Eligibility requirements for this study included (a) disease duration of at least 9 months, (b) fluency in English, and (c) at least 3 months on the present prescribed regimen. The only exclusion criterion was the presence of another serious concurrent condition that could affect HRQOL. Nine participants were included with mild asthma or thyroid problems, whereas youths with cognitive delay or serious medical conditions (e.g., moderate to severe asthma or juvenile rheumatoid arthritis) were excluded. Owing to the geographic location of the recruitment sites, the sample was ethnically diverse, consisting of 78 (49%) Caucasian, 62 (39%) Hispanic, and 19 (12%) Black youths, who identified as Caribbean Black (n = 5) or African American (n = 14). Six participants who identified as “Other” were excluded from the present analyses. The mean Hollingshead Four Factor Index of Social Status (Hollingshead, 1975) for this study sample was 39.9, indicating a mostly middle-class sample. However, socioeconomic backgrounds ranged from low (minimum = 11.0) to upper class (maximum = 66.0). Thirty-three percent of the families reported single-parent status.

Most of the youths (73.8%) were prescribed an injection regimen with a subset of children (26.3%) using insulin pump therapy. Those on injection regimens were prescribed an average of 2.6 injections per day. The youth in this study had diabetes for a mean of 4.62 years (SD = 3.06 years). The mean HbA1c of recruited participants at the university-based outpatient clinic was 9.72% (SD = 2.48). However, there was a wide range of HbA1c (6–16.9%). The mean HbA1c of recruited participants at the community-based outpatient clinic was 7.94% (SD = 1.43). Here also there was a wide range of HbA1c (5.3–12.8%). HbA1c values from the two sites are not comparable and have been standardized elsewhere as described in the Procedure section. Overall, the sample was in fairly good control, with a mean of 0.24 diabetes-related hospitalizations in the past year.

Procedure

Participants were recruited from two sites, a university-based outpatient clinic and a community-based outpatient clinic. Parents of children who met criteria for the study were approached at their regularly scheduled clinic visit. After a complete explanation of the objectives and procedures, consent and assent were obtained. The participation rate was 90%, with most of those declining consent doing so due to time constraints.

Parents were interviewed to obtain demographic information. Both parents and youths were then given the HRQOL questionnaires by a trained research assistant. As described by Varni et al. (2001), the PedsQL modules were self-administered with the exception of the child report form for 5–7-year-olds, which was administered in an interview format. All other questionnaires were self-administered and were only given to youths 8–17 years old and parents. The questionnaires
took about 45 minutes to complete and participants were given a $10 gift coupon for their participation. Finally, medical information for each participant was collected by reviewing medical charts. This research protocol was approved by the local institutional review board.

**Measures**

**Parent Interview**
Information collected included the youth’s age and ethnicity, as well as the parents’ marital status, occupation, and education level. Socioeconomic status (SES) was calculated using the Hollingshead Four Factor Index of Social Status (Hollingshead, 1975). Hollingshead scores could not be calculated for 49 of the participants due to incomplete parent information about occupation. Therefore, the highest grade completed by a parent was used in final analyses as a proxy measure of SES.

**Medical Chart Review**
Research assistants retrieved health information through medical chart review. In this study, this included the number of diabetes-related hospitalizations, the results of HbA1c assays, and the number of injections prescribed daily. Out of 118 participants prescribed insulin injections, there was complete data in the chart on the number of injections prescribed for only 92 (78%) participants. Assay machine data from two different sites were standardized using the upper limit of normal. The upper limit of normal is considered 6.1% (university-based clinic) or 6.4% (community-based clinic) depending on the HbA1c assay used. Therefore, HbA1cs presented for the entire sample are percentages of the upper limit of normal.

**Child Adjustment Factors**
Participants from the age of 8–17 completed the Behavior Assessment System for Children’s Self-Report of Personality (BASC–SRP). This study used the Emotional Symptoms Index (ESI) and adjustment composites to measure self-reported child adjustment. Parents of all participants completed the BASC–Parent Rating Scale (BASC–PRS); the Behavioral Symptoms Index (BSI); and Adaptive Skills composites were used to measure parent-reported child adjustment. Both the BASC–SRP and the BASC–PRS have satisfactory internal consistency, test–retest reliability, construct and criterion-related validity. Internal consistency for the composites used ranges from the high .80s to the mid .90s, and validity was established by comparing groups of children with preexisting clinical diagnoses to healthy children (Reynolds & Kamphaus, 1992). Concurrent validity is strong. The BASC–SRP is highly correlated with the youth self-report (Achenbach, 1991), whereas the BASC–PRS is highly correlated with the Child Behavior Checklist (Achenbach & Edelbrock, 1983) and Conners’ Parent Rating Scales.

**Parent Adjustment Factors**
The Perceived Stress Scale (PSS) (Cohen, Kamarck, & Mermelstein, 1983) was completed by parents as a measure of experienced levels of stress in the past month. Cohen and colleagues have demonstrated adequate reliability (.84–.86), discriminant validity with depression scales, convergent validity with life-event scores, and predictive validity of utilization of health services. The Beck Depression Inventory (BDI) was completed by parents in this study to measure depressive symptoms. The BDI is a widely used measure with good to excellent reliability (.73 to .92), concurrent validity established using the Hamilton Psychiatric Rating Scale for Depression and MMPI Depression Scale, and adequate discrimination of patients with major depressive disorder (Beck & Steer, 1993; Corcoran & Fischer, 1987).

**Family Adjustment Factors**
Participants from the age of 8–17 and parents completed the Cohesion and Conflict subscales of the Family Environment Scale (FES). These subscales measure the extent to which family members are helpful, supportive, and committed to one another, and the extent to which conflictual interactions are characteristic of the family system respectively. The FES and its various subscales are widely used and have adequate internal consistency (ranging from .61 to .78) and test–retest reliability (ranging from .68 to .86) (Moos, 1975). FES subscales are highly correlated with the Social Support Questionnaire (Sarason et al., 1983) and the Family Adaptability and Cohesion Evaluation Scales (FACES-II; Dickerson & Coyne, 1987), in addition the FES has been shown to discriminate distressed families from normal families.

**HRQOL Outcome Measures**
The PedsQL is a system of measures divided into Generic Core (23 items) and disease-specific (28 items) modules. Children and parents are asked to respond as to how much of a problem each item has been for the child in the past month. The Generic Core is comprised of subscales including items about physical, emotional, social, and academic functioning, and the diabetes-specific module is comprised of items about diabetes symptoms, treatment barriers, treatment adherence, worries and communication about the disease. For example, a generic item asks how much of a problem has the child
had paying attention in class, and a diabetes-specific item asks how much of a problem has the child had feeling tired or fatigued. There are three versions of child-report forms: young children (ages 5–7), school-age children (ages 8–12), and adolescents (ages 13–18). The various age-specific versions of the PedsQL differ in terms of developmentally appropriate language; for 5–7-year-olds, the response scale is simplified and corresponds to pictorial representations.

The validity of the Generic Core was established by determining that scores both differentiated between healthy youths and youths with an illness and were correlated with disease impact (Varni et al., 2001). The diabetes module of the PedsQL has also been shown to discriminate between healthy children and children with diabetes (Varni et al., 2003). It is made up of five subscales, which were each combined into a total score in this study. The subscales comprising the Generic Core (child report, .71 to .84; parent-report, .73 to .85) and Diabetes Module (child report, .63 to .81; parent report, .68 to .84) have previously been shown to have adequate internal consistency (Varni et al., 2003). In this study, total scores were used, and both child (Generic $\alpha = 0.84$, diabetes-specific $\alpha = 0.84$) and parent-report (generic $\alpha = 0.89$, diabetes-specific $\alpha = 0.89$) were internally consistent.

**Statistical Analyses**

After analyzing descriptive statistics, differences between participants at the two recruitment sites were examined. Independent samples t tests and chi-square tests were conducted to select control variables for the primary analyses. Analyses of covariance (ANCOVAs) were conducted to determine whether or not HRQOL differed significantly for youths on insulin pump therapy compared to those on injection regimens. Of interest were parent and child report for youths from 5 to 17 years of age on both generic- and diabetes-specific QOL.

Pearson correlations and factor analysis were used to achieve data reduction of the various psychosocial variables for the secondary analyses. Because of our interest in obtaining child report of psychosocial functioning along with parent report, these analyses excluded the 48 youngest participants, 5–7-year-olds, in our sample. Stepwise regression equations were used to determine which demographic and clinical variables would be entered in the final regression model. Finally, three block hierarchical regression analyses were conducted to identify demographic, clinical, and psychosocial variables that are significantly related to both generic- and diabetes-specific QOL in this population.

All psychosocial composites achieved through factor analysis were included in the final regression analyses.

**Results**

**Preliminary Analyses**

Mean child report of generic QOL was 79.00 ($SD = 12.80$), and mean parent report of generic QOL was 79.61 ($SD = 13.50$). Diabetes-specific QOL tended to be rated lower than generic QOL, with child report being a mean of 69.40 ($SD = 13.37$) and parent report being a mean of 70.03 ($SD = 13.64$). Also, a preliminary analysis compared youths on two or fewer injections to those on three or more injections and found no differences in child-, $t(89) = .95$, $p = .35$, and parent-rated, $t(87) = –.13$, $p = .90$, generic QOL, or in child-, $t(88) = 1.34$, $p = .18$, and parent-rated, $t(87) = .92$, $p = .36$, diabetes-specific QOL. There were also no differences in age, duration of diabetes, family conflict, child distress, conduct problems, or parent distress between the two groups. Therefore, in all of the following analyses youths on injection regimens were combined.

Chi-square analyses and independent samples t tests were used to compare participants at the two recruitment sites. Participants at the university site were found to have significantly higher mean HbA$_{1c}$, $t(68.7) = 6.05$, $p < .001$, and parents with less education, $t(153) = –2.74$, $p < .01$. Further, participants at the university site were more likely to be prescribed insulin pump therapy, $\chi^2(1) = 12.48$, $p < .001$, more likely to live in a one-parent household, $\chi^2(1) = 5.21$, $p < .05$, and more likely to be Black, $\chi^2(1) = 24.19$, $p < .001$ or Hispanic; $\chi^2(1) = 50.08$, $p < .001$, than White (non-Hispanic). There were no differences across sites in age, gender, or disease duration.

**First Aim: Comparing Two Regimens**

Table I summarizes data from chi-square analyses and independent samples t-tests used to compare youth on insulin pump therapy to those on injection regimens. Significant differences were found in the frequency of insulin pump use across ethnicities, $\chi^2(2) = 8.58$, $p < .05$. Post hoc analyses indicate that Caucasian youth were more likely to be on insulin pump therapy than both Black, $\chi^2(1) = 4.60$, $p < .05$, and Hispanic, $\chi^2(1) = 5.67$, $p < .05$, youth. Significant differences were found in parents’ level of education, $t(93.73) = –3.09$, $p < .01$, duration of diabetes, $t(148) = –3.23$, $p < .01$, and the child’s HbA$_{1c}$, $t(121.09) = 3.23$, $p < .01$. Levene’s test was used to identify analyses where the variances of the two groups were significantly different, in which case the appropriate adjusted t value and degrees of freedom are reported.
Table I. Demographic and Disease Characteristics of the Injection and Pump Therapy Groups

<table>
<thead>
<tr>
<th></th>
<th>Conventional insulin injection (N = 118) [n (%)]</th>
<th>Insulin pump therapy (N = 42) [n (%)]</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child gender: female</td>
<td>62 (52.3%)</td>
<td>25 (59.5%)</td>
<td>.435</td>
</tr>
<tr>
<td>Single-parent status</td>
<td>42 (35.6%)</td>
<td>11 (26.2%)</td>
<td>.144</td>
</tr>
<tr>
<td>Child ethnicity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>17 (14.4%)</td>
<td>2 (4.8%)</td>
<td>.014</td>
</tr>
<tr>
<td>Hispanic</td>
<td>51 (43.2%)</td>
<td>11 (26.2%)</td>
<td>.014</td>
</tr>
<tr>
<td>White (non-Hispanic)</td>
<td>50 (42.4%)</td>
<td>28 (55.7%)</td>
<td>.014</td>
</tr>
<tr>
<td>Child age (M ± SD)</td>
<td>10.86 ± 3.76</td>
<td>10.85 ± 3.37</td>
<td>.977</td>
</tr>
<tr>
<td>Hollingshead score (M ± SD)*</td>
<td>39.00 ± 13.37</td>
<td>42.50 ± 11.66</td>
<td>.212</td>
</tr>
<tr>
<td>Caregiver education (M ± SD)</td>
<td>5.19 ± 1.17</td>
<td>5.73 ± .85</td>
<td>.003</td>
</tr>
<tr>
<td>Disease duration (M ± SD)</td>
<td>4.13 ± 2.81</td>
<td>5.87 ± 3.36</td>
<td>.002</td>
</tr>
<tr>
<td>Standardized HbA1c (M ± SD)</td>
<td>142.05 ± 37.86</td>
<td>125.77 ± 22.26</td>
<td>.002</td>
</tr>
</tbody>
</table>

*Due to incomplete occupation information, N = 114 for Hollingshead means and standard deviations.

Four one-way ANCOVAs were conducted with HRQOL total scores as the dependent variables. The covariates in each analysis included ethnicity/race, which was defined as white versus minority due to the above results from the chi-square analyses; also included as covariates were parent’s education, duration of diabetes, and HbA1c. The independent variable, regimen type, included two levels: injection regimen or insulin pump therapy. A preliminary analysis evaluating the homogeneity-of-slopes assumption indicated that the relationships between the covariates and the dependent variable did not differ significantly as a function of the independent variable. The ANCOVAs for child and parent report of generic- and diabetes-specific QOL were not significant. Table II includes adjusted means, Fs, p-values, and partial η²s for each ANCOVA. It should be noted that these effect sizes indicate that the proportion of the variance of the dependent variable related to regimen type was minimal. Therefore, regimen type was not included in our secondary analyses.

**Second Aim: Factors that Contribute to Generic- and Diabetes-Specific QOL**

Before conducting the secondary analyses proposed in this study, the data collected on psychosocial measures was reduced using factor analysis. The number of factors to rotate was determined by a priori hypothesis based on consideration of questionnaire content and the interpretability of the factor solution. Consequently, four factors were rotated using a Varimax rotation procedure. The rotated solution, as summarized in Table III, yielded the four a priori interpretable factors. The family maladjustment factor accounted for 23.94%, the child distress factor accounted for 18.89%, the child behavior problems factor accounted for 17.32%, and the parent distress factor accounted for 16.19% of the variable variance. None of the measures loaded on more than one factor.

Stepwise regression equations were conducted with demographic variables (age, gender, parent education, ethnicity coded in two dummy variables, and parent marital status) and clinical variables (diabetes duration and standardized HbA1c) as possible predictors. The p-value for entry into the model was set at .05, and the p-value for removal was set at .10. Child report of generic QOL was predicted by age only, α = .21, p < .001; F(1, 133) = 5.84, p < .05, with older children reporting better QOL. There were no significant predictors for child report of diabetes-specific QOL. Parent report of generic QOL was predicted by both gender (α = -.18, p < .05) and HbA1c, α = -.23, p < .01; F(2, 127) = 6.27, p < .01, with boys and youths with better glycemic control having better parent-reported QOL. Finally, parent report of diabetes-specific QOL was predicted by age only, α = -.21, p < .05; F(1, 128) = 5.72, p < .05, with parents of younger children reporting better QOL for their children. Parental education, marital status, and ethnicity were unrelated to QOL.

The final regression models were conducted with seven variables in three blocks, to test the increment in variance accounted for by demographic, clinical, and psychosocial factors. The first block contained child age and gender, the second block included only HbA1c, and the final block was made up of the four psychosocial factors: child distress, child behavior problems, parent distress, and family maladjustment. Table IV summarizes the indices to indicate the relative strength of the individual factors and the incremental variance accounted for by each block. First, the final model explained 29% of the variance in child report of generic QOL, F(7, 76) = 4.34,
Only child distress and family maladjustment significantly contributed to the model. Second, the final model explained 25% of the variance in child report of diabetes-specific QOL, $F(7, 76) = 3.52$, $p < .01$. Again, only child distress and family maladjustment significantly contributed. Third, the final model explained 41% of the variance in parent-report of generic QOL, $F(7, 76) = 7.60$, $p < .001$. Child behavior problems, parent distress, and family maladjustment all significantly contributed. Finally, the final model explained 37% of the variance in parent-report of diabetes-specific QOL, $F(7, 76) = 6.36$, $p < .001$. Again, child behavior problems, parent distress, and family maladjustment all significantly contributed.

### Discussion

Given the current trend of intensifying treatments for type 1 diabetes, this study contributes to the literature by comparing the HRQOL of youths on insulin pump therapy to those on injection therapies. Also, this study explored the relative contributions of demographic, clinical, and psychosocial factors to HRQOL. These psychosocial factors include child, parent, and family adjustment variables. The PedsQL Generic Core and Diabetes Module were used in this study. This measure has been praised as a promising and thoroughly developed assessment of HRQOL for many different disease populations (Eiser & Morse, 2001). In this study, there were no differences in HRQOL of youths on insulin pump therapy as compared to those on injection regimens. Further, this study found that HRQOL is better predicted by measures of psychosocial adjustment than by diabetes-specific clinical measures.

The literature on HRQOL in youths with type 1 diabetes has focused largely on adolescent self-report of disease-specific QOL. This study included measurement of both generic- and disease-specific HRQOL from the child and parent perspective, as well as inclusion of a wider age range of diverse youths with type 1 diabetes (5–17 years old). Also, the importance of including both child and parent-report was evident. Although child and parent average HRQOL ratings were similar, the two outcomes were related to different factors in the final analyses.

This study also contributes to the literature by inclusion of an ethnically diverse sample of youths. However, present findings did not reveal any differences in HRQOL among the three broad ethnic groups. Significant differences existed in the glycemic control, parent
education level, single-parent status, ethnicity, and pre-
scription practices at the two recruitment sites. Therefore,
all possibly confounding variables were entered as
covariates when comparing pump users and injection
users on HRQOL.

Insulin pump users in this sample differed from
injection users across several domains. Youths pre-
scribed insulin pump therapy were more likely to be
white than either black or Hispanic, had parents who
were more educated, had better glycemic control, and
longer disease duration than injection-users. They did
not differ on age, gender, or parent marital status. The
confounding site differences and cross-sectional nature
of this study limit interpretation of these differences.
However, there is a great deal of evidence that pump
therapy results in improved glycemic control (Weissberg-
Benchell et al., 2003).

Although insulin pump therapy has been linked to
improvements in the health status of youths, it was not
related to better HRQOL in this sample. There are sev-
eral possible explanations for this finding. First,
although pump therapy provides health improvements
and increased flexibility, it also requires education, fre-
cquent blood glucose monitoring, calculation of carbo-
hydrate intake, and careful consideration of physical
activity. There is evidence that managing intensive reg-
imens can be stressful for some families (Whittemore
et al., 2003). Research looking at the perceived burden
of different aspects of pump therapy is needed. Sec-
ondly, pump therapy requires youths to wear a poten-
tially visible medical device. There is a need for
research looking at its possible impact on social inter-
actions. Finally, there is evidence that glycemic con-
trol, as measured by HbA1c, is either weakly related or

Table IV. Final Regression Analyses using Demographic, Clinical, and Psychosocial Variables to Account for Variance in Youths’ Health-Related
Quality of Life (HRQOL)

<table>
<thead>
<tr>
<th>Block</th>
<th>Independent variables</th>
<th>F(7, 76)</th>
<th>R²</th>
<th>R² change</th>
<th>β</th>
<th>t</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Generic QOL (child report)</td>
<td>4.34***</td>
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*p = .05. **p = .01. ***p = .001.
unrelated to HRQOL (Hoare et al., 2000; Ingersoll & Marrero, 1991). However, research indicates that improved glycemic control reduces the risk for long-term complications (DCCT, 1993). Long-term complications have been associated with reduced HRQOL in adults (Hahl et al., 2002). Therefore, longitudinal studies are needed to determine whether clinical improvements associated with pump therapy will ultimately lead to better HRQOL through a reduction in long-term complications. It is a limitation of this study that duration on the insulin pump was not measured and tested as a predictor of HRQOL.

Given that regimen type was unrelated to HRQOL in this study, it was excluded from analyses exploring predictors of generic and disease-specific HRQOL. In preliminary analyses age, gender, and HbA1c were significant predictors of HRQOL. Unlike prior studies, in this study self-reported HRQOL was not related to gender. However, gender was related to parent report of HRQOL in the expected direction, with boys perceived as having better HRQOL. Also, parents of youths with better glycemic control reported better generic HRQOL. Parent and child report differed with respect to age, with parents of younger children reporting better disease-specific HRQOL and older youths reporting better generic HRQOL. This difference may indicate a change in parent and youths’ perceptions about the disease and its management as older children and adolescents experience more independence and receive less supervision. One recent study indicated similarly small improvements in adolescent self-reported HRQOL, with less impact on family functioning over time (Hesketh et al., 2004). However, in the same study, parent report of adolescent HRQOL remained stable. Additional longitudinal research is needed to understand the developmental trajectory of generic and disease-specific HRQOL, and differences between child and parent report of HRQOL.

This study found that the relative contribution of psychosocial factors, including child, parent, and family adjustment variables, was significantly greater than the contribution of either demographic or clinical factors in predicting both generic- and disease-specific HRQOL. After including four psychosocial factors, all three of the previously significant demographic and clinical factors (age, gender, and HbA1c) became nonsignificant. In the final models, 29% of the variance in child-reported generic HRQOL was explained by only child distress and family adjustment, and these same variables explained 25% of the variance in child-reported disease-specific HRQOL. Child behavior, parent distress, and family adjustment explained 41% and 37% of parent-reported generic and disease-specific HRQOL respectively. Although health indicators such as glycemic control have not consistently been associated with HRQOL, there is support for the relationship between HRQOL measures and psychosocial variables such as depressive symptoms and family adjustment (Grey et al., 1998; Laffel et al., 2003). Consistent with prior studies, this study found significant relationships between HRQOL and child distress, parent distress, child behavior problems, and family maladjustment. In addition, one study of 170 adult type 1 diabetes patients found that neither the duration of the disease nor the intensity of treatment predicted HRQOL, but that other “nondiabetic” factors including social relationships and family arguments were significant predictors of HRQOL (Parkerson et al., 1993).

In summary, the results of this study indicate that HRQOL in youths with type 1 diabetes is not associated with regimen type. However, past research does indicate impressive health outcomes associated with insulin pump therapy. Although use of the pump has been associated with better glycemic control, these findings indicate it does not adversely affect HRQOL in children or adolescents. The nonrandomized nature of this study is a limitation. More longitudinal research is needed on this intensive regimen because of its demonstrated advantages, as well as its growing popularity (Kaufman et al., 1999). Further, this study provides evidence that disease-related factors, including clinical indicators and regimen type, do not account for HRQOL in youths with type 1 diabetes. Both generic and diabetes-specific QOL were significantly related to psychosocial adjustment more strongly than to demographic or disease indicators. Therefore, interventions seeking to improve glycemic control alone are unlikely to directly improve HRQOL. In fact, this study indicates that, to the extent that HRQOL is considered an important treatment outcome, interventions targeting psychosocial adjustment should be considered an important part of diabetes management and offered along with interventions designed to improve glycemic control.

Acknowledgments

This research was partially supported by a research training grant from the National Institutes of Health (HD07510).

Received April 27, 2005; revisions received August 24, 2005, and October 12, 2005; accepted October 25, 2005
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