Quality-of-Life Measures in Children and Adults With Type 1 Diabetes

Juvenile Diabetes Research Foundation Continuous Glucose Monitoring randomized trial

JUVENILE DIABETES RESEARCH FOUNDATION CONTINUOUS GLUCOSE MONITORING STUDY GROUP*

OBJECTIVE — To evaluate the impact of continuous glucose monitoring (CGM) on quality of life (QOL) among individuals with type 1 diabetes.

RESEARCH DESIGN AND METHODS — In a multicenter trial, 451 children and adults with type 1 diabetes were randomly assigned to CGM treatment or the control group. Generic and diabetes-specific QOL questionnaires were completed at baseline and 26 weeks by all participants and parents of participants <18 years old, and the CGM satisfaction scale was completed by the CGM group (participants and parents) at 26 weeks.

RESULTS — After 26 weeks, QOL scores remained largely unchanged for both the treatment and the control group, although there was a slight difference favoring the adult CGM group on several subscales ($P < 0.05$). There was substantial satisfaction with CGM technology after 26 weeks among participants and parents.

CONCLUSIONS — Baseline QOL was high, and the measures showed little change with CGM use, although a high level of CGM satisfaction was reported.

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In the Juvenile Diabetes Research Foundation (JDRF) Continuous Glucose Monitoring (CGM) trial, real-time CGM improved glycemia for adults with type 1 diabetes with entry A1C ≥7.0% (1–3), and more frequent CGM use was associated with a greater reduction in A1C in all age-groups (2). Participants with A1C <7.0% at enrollment who used CGM maintained low A1C levels more often than those who used standard blood glucose monitoring (BGM) and also had reduced biochemical hypoglycemia (3). This analysis assesses change in quality of life (QOL) among adults and children with type 1 diabetes and parent-proxy reports of youth QOL for participants in the trial.

RESEARCH DESIGN AND METHODS

— The protocol was approved by the institutional review boards of the participating centers. Written informed consent was obtained from subjects aged ≥18 years and from parents/guardians of minors; subjects aged <18 years provided written assent. The study is listed on www.clinicaltrials.gov (NCT00406133). Study procedures have been described elsewhere (1–3). In brief, 451 individuals with type 1 diabetes were randomized to the CGM treatment group ($n = 122$, ≥18 years old; $n = 110$, <18 years old) or to the control group ($n = 106$, ≥18 years old; $n = 113$, <18 years old). CGM subjects were instructed to use the CGM daily if possible; subjects in the control group were instructed to perform BGM ≥4 times per day. There were six scheduled visits and one scheduled call between visits to review glucose data and adjust management. All supplies were free to participants.

Measures

Diabetes-specific and general assessments of QOL were conducted at baseline and 26 weeks for all participants and parents of participants <18 years old. Participants ≥18 years old completed the Hypoglycemia Fear Survey (HFS) (4–6), Problem Areas In Diabetes (PAID) scale (7), and Social Functioning Health Survey (SF-12) version 2 (8). HFS includes questions about hypoglycemia fear (worry subscale) and behaviors to prevent low blood glucose (behavior subscale) (5). PAID assesses psychosocial adjustments related to diabetes and includes questions about anger, interpersonal distress, and frustration with diabetes treatment (7). SF-12 includes the mental component summary (MCS) and physical component summary (PCS) (8). Participants <18 years of age completed the HFS worry subscale (4,6) and selected subscales from the Pediatric Quality of Life Inventory (PedsQL)-Generic and Type 1 Diabetes Module developed by J.W. Varni et al. (9,10). Parents of participants <18 years of age completed the HFS worry subscale (4,5), the PAID-Parent (PAID-P) survey evaluating parental burden associated with diabetes care (11), and parent-proxy versions of the same PedsQL-Generic and Type 1 Diabetes Module subscales completed by their children (9,10). Additionally, the CGM satisfaction (CGM-SAT) questionnaire was administered to the CGM group (participants and parents) at 26 weeks to assess satisfaction with and perceived therapeutic impact of CGM (12).

Statistical methods

Primary analysis compared treatment groups at 26 weeks using ANCOVA models, separately for adults (≥18 years old), children (<18 years old), and their parents. Change from baseline to 26 weeks

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*A list of the writing committee can be found in the APPENDIX, and a complete list of the Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group is included in the online appendix available at http://care.diabetesjournals.org/cgi/content/full/dc10-0331/DC1.

Table 1—*Baseline and 26-week values for QOL and HFS measures for adults (≥18 years old at enrollment), youth (<18 years old), and parents of youth in the CGM and control groups*

	Baseline		26 weeks		Comparison
	CGM	Control	CGM	Control	*P**
Participants ≥18 years					
n	122	106	120	106	
HFS					
Total score†	37.4 ± 12.8	37.8 ± 14.3	33.3 ± 11.5	36.0 ± 13.6	0.04
Worry subscale‡	30.1 ± 18.3	30.6 ± 18.3	25.3 ± 15.8	27.7 ± 17.3	0.12
Behavior subscale§	46.9 ± 11.0	47.3 ± 13.1	43.8 ± 11.2	46.8 ± 13.3	0.03
PAID‖	22.7 ± 15.3	21.7 ± 18.0	18.1 ± 14.1	18.2 ± 14.6	0.50
SF-12					
PCS¶	54.1 ± 5.9	54.1 ± 7.2	55.5 ± 4.9	54.1 ± 6.9	0.03
MCS#	49.5 ± 8.4	48.2 ± 10.0	48.4 ± 10.1	48.7 ± 9.6	0.35
Participants <18 years					
n	107**	111	103**	106	
HFS worry subscale‡	25.7 ± 16.6	25.9 ± 14.9	20.8 ± 13.1	22.6 ± 14.4	0.27
PedsQL					
Generic††	78.5 ± 12.5	79.7 ± 11.7	80.5 ± 12.4	81.4 ± 12.0	0.96
Diabetes-specific‡‡	82.2 ± 12.2	81.6 ± 12.9	81.7 ± 12.9	82.6 ± 13.2	0.28
Parents§§					
n	110	113	107	107	
HFS worry subscale‡	41.5 ± 16.0	42.2 ± 19.8	37.0 ± 14.6	38.0 ± 17.2	0.88
PAID-P¶	46.3 ± 14.0	43.8 ± 15.9	47.1 ± 12.7	43.8 ± 17.0	0.25
PedsQL					
Generic††	76.7 ± 11.8	77.2 ± 13.7	76.7 ± 12.6	77.5 ± 13.5	0.70
Diabetes-specific‡‡	76.0 ± 12.1	75.7 ± 14.2	76.5 ± 11.6	74.6 ± 13.3	0.28

Data are means ± SD unless otherwise indicated. These analyses were limited to subjects or parents who completed baseline questionnaires. Six children randomized into the study did not complete baseline questionnaires and were excluded from analysis. **P* value was from ANCOVA controlling for baseline value. †Average score of all items giving equal weight to each item. Scale 0–100 with higher score denoting more fear or more likely to avoid low blood glucose. ‡Scale 0–100 with higher score denoting more fear. §Scale 0–100 with higher score denoting more likely to avoid low blood glucose. ‖Scale 0–100 with higher score denoting more problems. ¶Norm-based score with higher score denoting better functioning. #Norm-based score with higher score denoting better functioning.**One participant <18 years old in the CGM group completed only the HFS at baseline and was excluded from analyses of the PedsQL surveys at baseline ($n = 106$) and at 26 weeks ($n = 102$). ††Scale 0–100 with higher score denoting higher QOL. ‡‡Scale 0–100 with higher score denoting higher QOL. §§Parents refer to parents of participants <18 years of age.

was the dependent variable, and models were adjusted for baseline values. A secondary analysis was conducted to examine QOL by frequency of CGM use. Analyses were performed with SAS version 9.1 (SAS Institute, Cary, NC).

RESULTS — Survey completion was high (CGM group: adults 98%, youth 93%, parents 97%; control group: 100, 94, and 95%, respectively). Mean A1C at enrollment was 7.4% for both groups. Baseline QOL scores were similar for the CGM and the control group (Table 1). At 26 weeks, there was a slight ($P < 0.05$) improvement favoring the CGM group for participants ≥18 years old for the HFS total score, HFS behavior subscale, and the SF-12 PCS subscale. There were no differences in scores for youth or their parents for any measures after 26 weeks. Results were similar in subgroups based on baseline A1C (≥7.0%, <7.0%) and by CGM usage (<6 days/week, ≥6 days/week) (online Appendix 1, available at http://care.diabetesjournals.org/cgi/content/full/dc10-0331/DC1).

CGM-SAT scores at 26 weeks were higher than neutral (3.0 on a 5.0 point scale) for adults, youth, and parents, with mean ± SD scores of 3.9 ± 0.5, 3.6 ± 0.5, and 3.8 ± 0.5, respectively, and were higher for those who used CGM more frequently (comparing CGM use ≥6 days/week with use <6 days/week: mean CGM-SAT score 4.0 vs. 3.7 for participants ≥18 years old, 3.8 vs. 3.4 for participants <18 years old, and 3.9 vs. 3.7 for parents).

CONCLUSIONS — None of the QOL measures showed meaningful differences between the CGM treatment and control groups after 26 weeks, although there was a suggestion of a QOL benefit favoring the CGM group on a few measures among adult participants. Lack of meaningful differences could be due to lack of benefit of CGM use on QOL, insensitivity of the measures to detect changes, or high baseline levels of QOL in this population yielding a ceiling effect. In comparing scores on the baseline surveys with those from population norms, we found that adult participants had comparable scores on the SF-12 (8) to individuals without diabetes while scores on the PedsQL-Generic were comparable to population norms for children with type 1 diabetes or their parents (9). Because there is no reason to believe that CGM improves QOL to a level better than that of a disease-free population, the amount of improvement that could be measured in this study for adults may have been limited by the high QOL scores at enrollment. It is reassuring that QOL did not decline among the participants or parents when this new technology was initiated. Moreover, CGM-SAT scores were positive and indicative of substantial satisfaction with CGM.

The generalizability of these findings should be interpreted in the context of the

characteristics of the study participants who were predominantly non-Hispanic white, well-educated, privately insured, and most commonly treated with insulin pumps at enrollment. These characteristics may have contributed to their high QOL scores at baseline and/or mitigated any change in QOL associated with CGM use. While this trial provides preliminary insight into QOL after initiating use of CGM, studies conducted in more sociodemographically diverse individuals may help to fully characterize the impact of current CGM use on QOL of children and adults with type 1 diabetes.

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Below is a listing of relationships of the investigators with companies that make products relevant to the manuscript between 1 July 2006 and 26 October 2009. Research funds listed below were provided to the legal entity that employs the individual and not directly to the individual.

B.I. has received a speaker honorarium from DexCom. C.K. has received consulting fees from Medtronic MiniMed. L.L has received a speaker honorarium from LifeScan, consulting fees and a speaker honorarium from Abbott Diabetes Care, and consulting fees and research funding from Medtronic MiniMed. W.V.T. has received consulting fees from Abbott Diabetes Care, LifeScan, and Medtronic MiniMed, and a speaker honorarium and research funding from Medtronic MiniMed. No other potential conflicts of interest relevant to this article were reported.

The study was designed and conducted by the investigators. The writing group collectively wrote the manuscript and vouch for the data. The investigators had complete autonomy to analyze and report the trial results. There were no agreements concerning confidentiality of the data between the Juvenile Diabetes Research Foundation, the authors, or their institutions. The Jaeb Center for Health Research had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

J.M.L. and W.V.T. researched data, contributed to the discussion, wrote the manuscript, and reviewed/edited the manuscript. L.L., T.W., C.K., and K.J.R. researched data, contributed to the discussion, and reviewed/edited the manuscript. D.X. contributed to the discussion, wrote the manuscript, and reviewed/edited the manuscript. R.W.B. contributed to the discussion and wrote the manuscript. E.S.H. and J.L. contributed to the discussion and reviewed/edited the manuscript. B.I. researched data.

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