

Background and Methods for Evaluating Quality of Life in Children and Adolescents with Diabetes*

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The major aims of Diabetes care in children and adolescents are to achieve optimal glycaemic control (1-6), avoid frequent or severe hypoglycaemia and to promote normal psychosocial development with support for the child and family in developing strategies to cope effectively with a lifetime of diabetes. The challenge, therefore, is to maximise Quality of Life (QOL) for the child and family in the context of effective therapeutic intervention (7-8).

The relationship between QOL and psychosocial issues, diabetes treatment regimens and metabolic control in adolescents has been controversial (9-14). Some studies have suggested a link between QOL and metabolic control (11, 12) whereas others found no association (9, 13, 14). Parents and health professionals make assumptions about adolescents QOL in the context of diabetes. These assumptions may play a major role in diabetes management (12). It has been shown in other medical conditions that the views of adults and children are discordant (15, 16). It is important therefore to understand the views of the adolescent and also of the adult carers including parents and health professionals. Puberty poses special difficulties in diabetes management for physiological and psychological reasons. It is associated with poor metabolic control which may relate to decreasing adherence to treatment regimens (11, 13) and decreasing insulin sensitivity of peripheral tissues (17). These changes in metabolic control may affect QOL differently in males and females.

Health-related QOL is a multi-dimensional construct that refers to subjective and objective evaluations of dysfunction caused by an illness and its treatment. There are four major QOL domains which include disease state and physical symptoms, psychological, and social functioning (18). Other domains include academic achievement, neuro-psychological functioning, social functioning and satisfaction with life. QOL measurements enable evaluation of treatment, identification of major areas of stress, comparison between regimens and strategies, evaluation of education programme and comparison between centres.

There are two general types of QOL instruments, generic and specific. Generic measures assess the range of dimensions that comprise QOL and may be administered to different illness populations or groups of health individuals and the results can be compared across groups. Disease specific QOL measures assess concerns that may be particular to a disease, function or population. They are most likely to provide information that is clinically relevant, and thus may be more readily incorporated into clinical or research protocols than generic measures. Hence, there are trade-offs to consider when choosing between a generic and disease-specific measure. Ideally, the two types of measures may be used in a complementary fashion. QOL measures should be brief, easy to administer and score, be normed at various stages of disease and treatment, discriminate between stages of disease and level of dysfunction and assess the fre-

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quency of problems rather than estimates of the child's capacity.

The DQOL instrument was developed in the early 1980's for use in the diabetes control and complications trial (DCCT) by a multi disciplinary team (19). It is a multi dimensional construct and is a self-report measure that assesses subjective evaluations of the impact of diabetes on their function. It was originally designed to evaluate the relative burden of an intensive diabetes treatment regimen, with the goal of maintaining blood glucose levels as close as possible to those of people without diabetes, in comparison to standard diabetes therapy. Prior to the development of the diabetes QOL (DQOL), there were no available diabetes-specific or diabetes-oriented QOL measures. It was conceptualized as measuring the patient's personal experience of diabetes care and treatment. Four separate areas were addressed by the measure: satisfaction with treatment, impact of treatment, worry about the future effects of diabetes, and worry about social vocational issues. There is also a single overall well being scale. In addition to these 46 core items and the well being scale, the DQOL included 13 items to assess adolescent populations who are in school and/living at home with parents. Reliability and validation were demonstrated by high cronbach's alpha coefficient scores, high test-retest correlations. Face validity was demonstrated and also construct validity by correlations with the Symptom Checklist 90-R (SCL), the Bradburn Affect Balance Scale (ABS) and the Psychosocial, Adjustment of Illness Scale and Sensitivity to change (PAIS). The DQOL was subsequently modified and developed for youths by Ingersoll and Marrero for specific use in young people with diabetes (9). The instrument was shortened and school and peer related questions were added and in addition the wording was simplified. The result is an instrument composed of 3 inter correlated scale: a diabetes life satisfaction scale, a disease impact scale and a disease related worry scale and one general health perception question. Reliability levels were satisfactory. More recently other instruments have been developed for adolescents with diabetes such as the SEI QOL which is an individualised interview measure (20).

The DCCT showed that good glycaemic control in adults and adolescents delays the onset and slows

the progression of diabetes complications (1, 2). The achievement of good metabolic control is difficult in children and particularly in adolescents. The DCCT study patients were predominantly adults whilst only 195 (14%) were adolescents aged 13-17 years. The Hvidøre study group on childhood diabetes subsequently performed the first large study on metabolic control in a cross sectional study of 2873 children and adolescents with type I diabetes from 18 countries (3). This study showed that the overall glycaemic control in this study was comparable to that of the adolescent group in the DCCT, although the rate of hypoglycaemic events was slightly lower. The grand mean HbA1c value was $8.6 \pm 1.7\%$ (mean \pm SD) but varied significantly between centres, irrespective of the insulin regimen. The results of this study confirmed that blood glucose control, as assessed by HbA1c, was poorest during puberty. The elevated level of HbA1c (9.0-9.5%) was found despite the fact that 38% of these young people were on 3 or more insulin injections daily.

Both the DCCT and the recent ISPAD (1, 21) guidelines have recommended a treatment target for HbA1c of 7.5%. The achievement of good metabolic control is difficult in children and particularly in adolescents. It requires a complex intrusive and highly demanding daily programme for families. As paediatricians we have always been concerned that strict management may have negative effects on QOL for child and family. The results of QOL studies on children and adolescents with diabetes have been controversial and based on small numbers.

In order to assess the relationship between metabolic control and QOL in adolescents the Hvidøre study group in 1998 conducted a study on a large international cohort of adolescents with diabetes and their families (22). 2101 adolescents (1085 boys, 1016 girls) with type I diabetes from 21 centres in 17 countries in Europe, Japan and North America participated. The purpose of the study was to determine the relations between QOL and HbA1c, age, sex, duration of diabetes, Body Mass Index (BMI), insulin regimen, severe hypoglycaemia and family structure. Furthermore, the study aimed to compare adolescent QOL with parent and health professional perceptions of family burden related to diabetes. Clinical and demo-

graphic information was obtained and HbA1c was analysed centrally the Steno Diabetes Centre in Denmark.

QOL in adolescents was assessed using the adolescent version of the DQOL questionnaire developed by Ingersoll and Marrero (9). The questionnaire contains 52 items in 4 sections: impact of diabetes, worries about diabetes, satisfaction with life, and health perception. Questions were scored from 1-5 except health perception, which was scored from 1-4; a lower score indicates better QOL except question 8 in the impact section where scoring was reversed. In the original Ingersoll and Marrero instrument (9), lower scores in the satisfaction subscale indicated poorer QOL. For ease of comparison across sub-scales, all scales were scored in the same direction.

In order to evaluate perception of the family burden relating to diabetes among parents and health professionals, 2 new questionnaires were constructed for this study. A multi-dimensional self-rating questionnaire (9 questions) was constructed for parents to evaluate family burden relating to diabetes including: medical treatment, restrictions, family disruption, physical and psychological problems, and long-term health concerns. There were also questions relating to change in school performance, general health, and QOL experienced by the patient and family. Questions were scored from 1 to 5; a lower score indicated less burden or better QOL. This questionnaire could be completed by either parent.

A multi-dimensional self-rating questionnaire (10 questions) was constructed for health professionals to evaluate their perception of the family burden, psychological disturbance, adherence to medical recommendations, coping ability, QOL and social status and ethnicity of adolescents or families. Scoring was as for parent instrument. This questionnaire could be completed in a clinic setting by any health professional (e.g. doctor, nurse, dietician) familiar with the adolescent and family. For each adolescent, 1 parent and 1 health professional completed a 5 item questionnaire about their perceptions of the family burden relating to the adolescents diabetes. Questions were scored from 1-5; a lower score indicates less burden.

A pilot was performed using the three questionnaires. This showed that answers were scored less pos-

itively if adolescents answered a questionnaire alone. The scoring instructions were simplified as a result of this pilot study and some words were changed such as computer instead of typewriter.

Translation and cultural adaptation of the 3 questionnaires to each of the 14 languages in the study was performed by a forward translation from English followed by an independent backward translation into English, laypanel testing and final endorsement by the originators.

Questionnaire completion rates were very high for adolescents and health professional (93, 89, and 94% respectively), as were item completion rates for all 3 groups (98.6-99.8%). Cronbach's alpha coefficient values for the questionnaires were: adolescent DQOL impact 0.79, worries 0.84, and satisfaction 0.92; parents 0.80; and health professionals 0.86, indicating good internal validity and consistency of the multiple-item instruments.

This study showed that better metabolic control is associated with a better QOL for adolescents with a lower perceived burden by parents and health professionals. All QOL scores were linearly transformed, so that the best possible score was 0 and the worse possible was 100. A lower impact score was significantly associated with better HbA1c. Impact of diabetes was similar in boys and girls, and neither age nor duration of diabetes had an impact on the scoring. More worries were evident with increasing age, especially in girls. This may reflect the higher incidence of psychological disturbance widely reported in population studies of adolescent girls (17, 28-29). The relationship between HbA1c and worry was just significant. Less satisfaction was shown with increase in age and again this was more pronounced in girls. Higher HbA1c was associated with significantly less satisfaction. Health perception was significantly poorer in girls than in boys and the effect of HbA1c was highly significant for both sexes indicating that poor control was associated with significantly poorer health perception.

There was no correlation between adolescent QOL scores in either parent or health professional perceptions of family burden. Adolescents expressed less difficulty with diabetes than both adult groups. Also, patient and health professional ratings were on-

ly modestly correlated. These findings suggest the importance of assessing the perceptions of all 3 groups in the adolescent diabetes management triad. In contrast to the increasing worry and poorer satisfaction described by adolescents, parental assessment of family burden decreased with adolescent age, with parents of girls reporting the lowest burden. Because girls enter puberty earlier than boys, with an earlier transfer of responsibility for self-care management from parent to child, parental burden may be correspondingly decreased. By contrast, health professional scores for family burden showed no sex difference. For both parent and health professional ratings, higher HbA1c levels were associated with greater family burden.

There was no significant relation between the number of insulin injections per day (or use of pre-mixed insulin) and adolescent QOL or with family burden as assessed by parents and health professionals, even after adjustment for the effects of centre, sex, age, and duration of diabetes.

Greater BMI was associated with poorer adolescent-rated QOL, including lower satisfaction and worse health perception. It was not associated with impact of diabetes, worries, or family burden as described by parent or health professional.

Adolescents having two-parents at home had significantly lower HbA1c values compared with single parent families. Health professionals perceived family burden was significantly lower in two-parent than single parent families. Family structure had no significant effect on either parent scores for burden or adolescent scores for impact of diabetes, worries, satisfaction, or health perception. In the ethnic minority group HbA1c levels were significantly higher than in the non-ethnic group (9.2 vs 8.7%).

This is the first international, multi-language study evaluating the relationship between metabolic control and QOL in adolescents with diabetes. The study suggests that metabolic control is associated with a better QOL for adolescents and with a lower perceived burden by parents and health professionals. Although the study could not determine a cause of relationship, efforts to achieve optimal metabolic control now seem justified on QOL as well as clinical grounds. The size and international nature of the study adds credence to this assertion. Thus people with a higher

QOL may be more capable physically and psychologically to deal with the burdens of diabetes management and better QOL may facilitate better metabolic control through improved self-care as part of a positive cycle. The study suggests that specific attention should be given to the management of girls, single parent families and ethnic minorities, because QOL evaluations indicate particular problem in these groups. Assessments by parents and health professionals are recommended for use in diabetes care, because these appear to be unique end points that may influence treatment outcome independent of patient QOL.

The questionnaires were feasible, reliable and valid as diabetes QOL assessment tools for adolescents and the new questionnaires for parents and health professionals add a different perspective. Future studies are warranted to evaluate cross-cultural difference in diabetes related QOL and longitudinal relations between QOL and clinical outcomes.

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