

Health-related quality of life in relation to metabolic control and late complications in patients with insulin dependent diabetes mellitus

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To investigate important factors with respect to health-related quality of life (HRQOL) in patients with longstanding insulin dependent diabetes mellitus, a patient cohort was followed prospectively for 10 years. The degree of metabolic control and the presence of late complications was assessed and HRQOL was measured with a 61-item questionnaire (SWEDQUAL) in which reference values have been obtained in a population sample. The results indicate that diabetic patients ($n=108$) experienced a quality of life as good as a general population. When patients were divided into four groups based on metabolic control, those with poor control ($HbA_{1c} \geq 9\%$) rated their physical and emotional functioning significantly lower than those with lower HbA_{1c} values. Nearly 15% of the patients reported 1–5 hypoglycaemic episodes during the latest 6 months. Despite a lower HbA_{1c} they rated their general health as being poorer than patients without severe hypoglycaemia. Of the 108 patients 39% appeared to be free from late complications of diabetes. These patients rated their general health as better than patients who already had developed late complications. We conclude that a satisfactory metabolic control with a minimum of hypoglycaemic episodes is desirable not only to prevent late complications but also because poor metabolic control seems to be one reason why diabetic patients experience a poorer quality of life.

Key words: quality of life, diabetes mellitus, metabolic control, late complications.

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Introduction

Insulin dependent diabetes mellitus is a lifelong disease with a complex treatment schedule. To achieve good metabolic control, the diabetic patient usually needs to have profound knowledge about how to adjust insulin doses to different daily life situations. A treatment regime that diminishes the possibilities to act spontaneously is likely to affect quality of life.¹ However, poor metabolic control due to a lack of a strict regime could also be detrimental to quality of life in terms of physical attributes. Wikby and co-authors² found that patients with well-regulated diabetes rated their bodily health higher than other attributes of quality of life, while patients with a poor diabetes regulation showed lower ratings. In an earlier study,³ we also found that diabetic patients with good metabolic control rated their own physical health in relation to mental balance higher than those with poor control. Actually, the patients with acceptable intermediate metabolic control were those who gave the highest ratings on both physical and mental scales. Also, Nerentz *et al.*⁴ found that patients with tight glycaemic control had lower HRQOL-ratings than those with less tight control. These findings highlight the problem that was earlier discussed by Ternulf-Nyhlin,⁴ namely that it is a fine balancing act for the patient to be able to achieve good metabolic control of his/her diabetes without the treatment overly interfering with daily life activities.

The necessity of attaining good metabolic control is now generally agreed upon. This is because of the evidence indicating that poor metabolic control is directly related to the development of such microvascular late complications as retinopathy, nephropathy and neuropathy.^{5–11} The impact of late complications on the patients' quality of life may be investigated by various methods. Thus, it has been shown that

patients with neuropathic symptoms¹² and nephropathy^{13,14} have lower general health perceptions and worry more about their health than patients with no diabetic complications. Further, the awareness of a clear relation between metabolic control and the occurrence of late complications can give rise to anxiety and, thereby, give a lower quality of life regarding emotional factors.¹⁵

In this study, we particularly wanted to investigate health-related quality of life in IDDM patients and the relation that HRQOL might have with metabolic control and the presence of late complications.

Methods

Subjects

An original cohort of 185 insulin dependent diabetic patients (IDDM) were studied over a 10 year period. In 1984, the cohort consisted of all patients visiting the outpatient clinic at the University hospital in Uppsala. These patients fulfilled the following criteria: (1) born between 1939 and 1959; (2) onset of diabetes in 1975 or earlier; (3) treated with ≥ 20 U insulin daily. A detailed description of the patient population is given elsewhere.³

Since 1984, 36 patients moved out of the area and 18 died. Of the remaining 131 patients, 108 answered the quality of life questionnaire used in this study. Background and diabetes-related characteristics for the remaining patients are shown in Table 1.

Reference population. The reference group consists of

a random sample ($n=1,443$) from the Swedish population between 18–84 years of age. These data were collected by Brorson *et al.* in 1991 using SWEDQUAL as a measure of HRQOL. The results of the study were published in 1993.¹⁶

Measures

Health-related quality of life. HRQOL was measured with SWEDQUAL, a questionnaire (61 items) that measures seven dimensions of HRQOL: Physical functioning, role functioning, pain, sleep, emotional well-being, family functioning and general health perceptions.¹⁶ Items are scored (0–100) such that a high score indicates better health/more favourable health state. The reliability, which was calculated by using Cronbach's α coefficient, varied from 0.79–0.89 in the general population sample and from 0.77–0.94 in the current study with 108 diabetic patients.

Glucosylated haemoglobin (HbA1c). HbA1c was assayed by a liquid chromatographic method (Pharmacia FPLC System). The upper normal limit at our laboratory is 5.7%. The patients were classified into four metabolic groups on the basis of mean HbA1c values for 1 year (see Table 2).

Hypoglycaemia. The patients reported hypoglycaemic episodes by answering the following questions: "During the latest six months, have you experienced episodes of such a low blood glucose level that you needed help from others to manage the situation?" and "If yes, how many times did that happen during the last six months?"

Table 1. Background and diabetic related characteristics in patients included in the longitudinal follow-up in 1994

Characteristics	Patients in the study ($n=131$)	Patients answering the HRQOL-questionnaire ($n=108$)
Gender		
Male	71 (54%)	55 (51%)
Female	60 (46%)	53 (49%)
Cohabitation		
cohabitant	93 (71%)	78 (72%)
non-cohabitant	38 (29%)	30 (28%)
Education		
≤ 9 years	54 (41%)	44 (41%)
> 9 years	77 (59%)	64 (59%)
Age (years, mean \pm sd)	43.7 \pm 5.6	43.5 \pm 5.7
Age at onset (years, mean \pm sd)	14.1 \pm 8.3	14.6 \pm 8.7
Duration of diabetes (years, mean \pm sd)	29.6 \pm 9.1	28.7 \pm 9.5
Mean HbA1c (%)	7.5 \pm 1.2	7.7 \pm 1.0

Table 2. Mean values for HbA1c in patients with good (HbA1c \leq 7.0%), acceptable (HbA1c=7.1–8.0%), unsatisfactory (HbA1c=8.1–9.0%) and unacceptable (HbA1c $>$ 9.0%) metabolic control (mean values during 1 year)

Metabolic control	Number of patients	HbA1c (%)	sd
Good	35	6.3	0.6
Acceptable	23	7.3	0.2
Unsatisfactory	26	8.0	0.3
Unacceptable	24	9.3	0.1

Late complications. The classification of 'retinopathic changes' was based on an ophthalmologist's evaluation of photometric examinations. The classification included three categories (no important retinopathic changes, simplex retinopathy and preproliferative-proliferative retinopathy) and was performed without knowledge of the patients' clinical status.

'Albuminuria' was defined as consistently positive Albustix[®] test strips or a 24 hour excretion $>$ 300 mg with a turbidometric method.

'Neuropathy' has been defined in terms of observed symptoms considered clinically relevant by the observer or verified by nerve velocity measurements. Based upon the above classifications, we used only a dichotomic representation; presence of late complications or absence of complications.

Socio-economic factors. Length of education is reported as low (\leq 9 years) or high ($>$ 9 years of education). Income is divided into three groups: low income \leq 150,000 SEK, medium income $>$ 150,000 \leq 225,000 SEK and high income $>$ 225,000 SEK. Type of daily work is categorized into two groups: manual workers and employees. Cohabitation is also categorized in two groups: living with a partner and single-living.

Procedure

The patients in this study have been followed since 1984. Metabolic and diabetes related data are collected continuously by nurses and physicians not directly involved in the study. Data on health-related quality of life were collected by use of a mailed questionnaire. The SWEDQUAL instrument was mailed to all 131 patients. After two reminders 108 (82%) of the patients answered the questionnaire.

Statistics

Computer program Statview 4.02 has been used for all analyses. Means and standard deviations have been calculated for the background characteristics and the metabolic data. The 95% confidence intervals and standard error have been used for the different groups when comparing health-related quality of life. ANOVA and χ^2 analyses have also been used for group comparisons. Stepwise regression analysis has been used for the purpose of prediction.

Results

Metabolic control

The mean value for HbA1c during the last year (mean of 3–4 determinations) was 7.6% (sd=1.2) in the total patient group ($n=108$). Mean values and sd's for four groups are shown in Table 2. These groups were formed according to arbitrary definitions that appear in Table 2.

HRQOL in diabetic patients compared with a general population sample

When HRQOL was measured with SWEDQUAL there were no significant differences between the whole material of diabetic patients and the Swedish general population sample published by Brorson *et al.* (1993) (see Figure 1).

HRQOL and level of metabolic control

When HRQOL was compared among patients with different levels of metabolic control, those with acceptable metabolic control had the highest ratings on most scales. Patients with poor control rated their physical and emotional functioning significantly lower than the others (Figure 2 and Table 3).

Late complications and level of metabolic control

Of the 108 patients 42 (38%) were free from late complications. Patients with poor metabolic control had significantly more often late complications (75% of the patients with unacceptable metabolic control had one or more late complications) when compared

Figure 1. Mean values of the HRQOL scales in 108 diabetic patients and in a Swedish general population ($n=1443$)

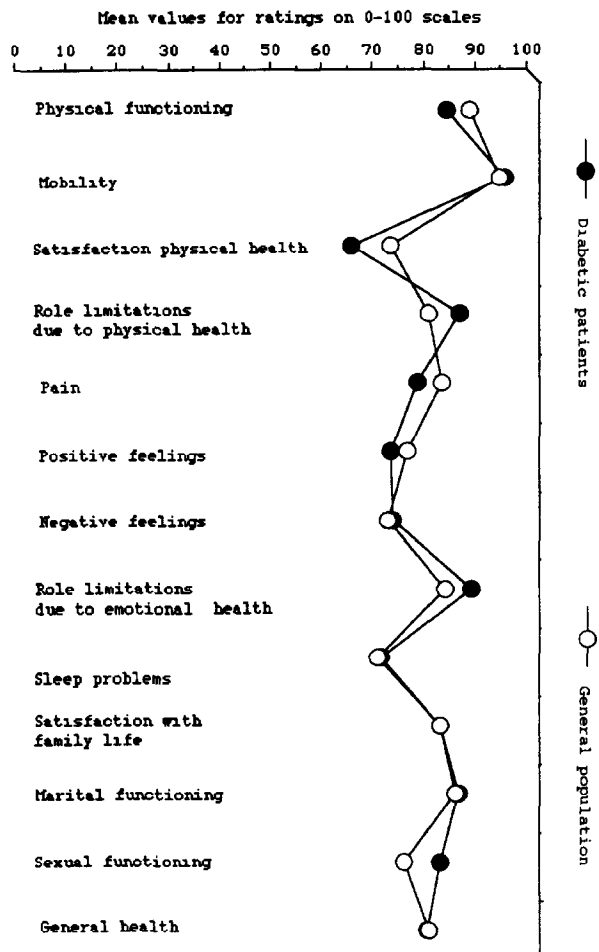


Figure 2. Mean values of the HRQOL scales in 108 diabetes patients with different levels of metabolic control

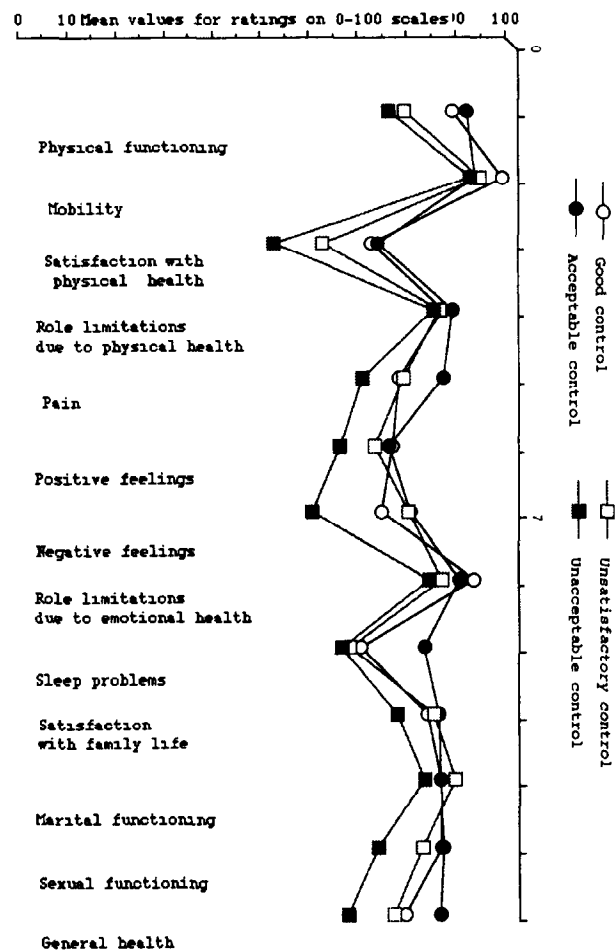


Table 3. Different dimensions of HRQOL in diabetic patients with good ($n=35$), acceptable ($n=23$), unsatisfactory ($n=26$) and unacceptable ($n=24$) metabolic control ($p < 0.05$)

Dimensions of HRQOL	Level of metabolic control		
	Good mean \pm sd	Acceptable mean \pm sd	Unsatisfactory mean \pm sd
Physical functioning	88.1 \pm 2.9	91.0 \pm 2.4	78.2 \pm 5.5
Mobility	98.1 \pm 1.3	92.4 \pm 4.2	93.6 \pm 3.7
Satisfaction with physical health	71.5 \pm 4.8	72.8 \pm 5.8	61.6 \pm 6.1
Role limitation due to physical health	86.0 \pm 4.4	87.9 \pm 6.4	85.5 \pm 4.8
Pain	77.1 \pm 6.2	86.2 \pm 5.8	78.1 \pm 6.8
Positive feelings	75.7 \pm 3.1	75.1 \pm 5.5	72.2 \pm 3.3
Negative feelings	73.6 \pm 5.0	79.3 \pm 5.1	78.9 \pm 4.2
Role limitation due to emotional health	92.2 \pm 3.0	89.4 \pm 5.8	85.9 \pm 4.6
Sleep	69.2 \pm 5.2	82.3 \pm 4.7	67.0 \pm 6.1
Satisfaction with family life	82.8 \pm 4.2	85.0 \pm 3.5	84.1 \pm 3.7
Marital functioning	85.5 \pm 3.4	85.3 \pm 5.2	88.3 \pm 4.1
Sexual functioning	85.6 \pm 4.0	86.1 \pm 4.7	81.9 \pm 6.6
General health	78.3 \pm 4.0	85.5 \pm 4.2	76.0 \pm 4.7

with those with better metabolic control, ($\chi^2=17.4$, $df=6$, $p=0.008$).

HRQOL and late complications

Figure 3 shows mean values and standard errors for health-related quality of life in patients with and without late complications. Patients with late complications were less satisfied with their physical health ($F=4.1$, $p=0.05$) compared with patients without complications. These patients also reported more pain ($F=5.5$, $p=0.02$) and a decline in sexual functioning ($F=6.7$, $p=0.01$). Limitations due to physical ($F=5.3$, $p=0.02$) and emotional health ($F=10.9$, $p=0.001$) were more prominent in the group with diabetic complications, and they also rated their general health as worse than the patients without complications ($F=17.1$, $p=0.0001$). Regarding the emotional factor, patients without complications scored higher on positive feelings than patients with diabetic complications ($F=4.1$, $p=0.04$). There were significant differences in metabolic control between these two groups. Patients without diabetic complications had a significantly better metabolic control than those with late complications ($7.3\% \pm 1.2$ vs. $7.8\% \pm 1.2$; $F=4.1$, $p=0.05$).

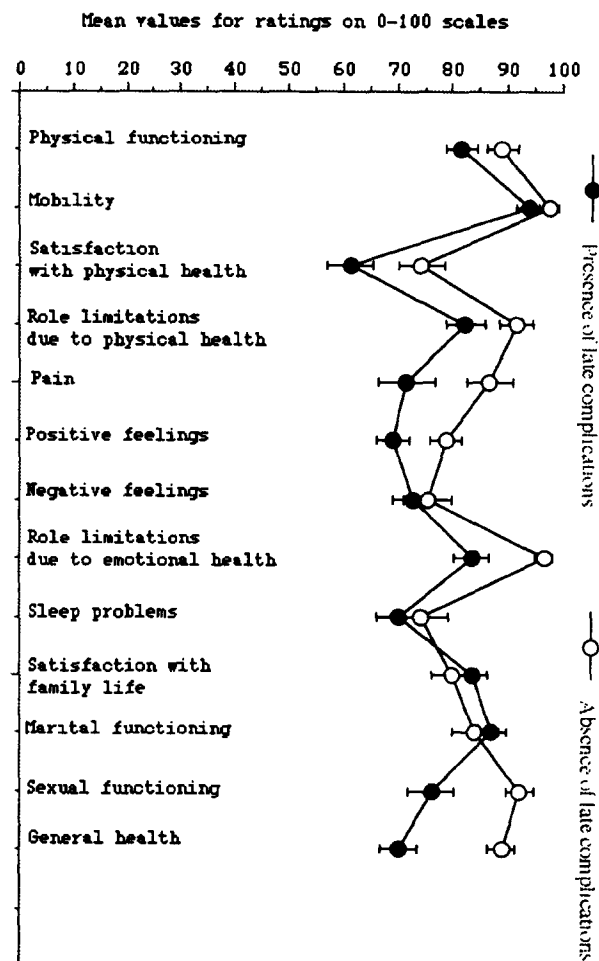
HRQOL and hypoglycaemia

Hypoglycaemic episodes that the patients were not able to manage themselves were reported by 14.7% of the patients. The number of episodes ranged from 1–5 during the latest 6 months ($Md=3$). Patients who reported episodes of hypoglycaemia had significantly lower HbA1c mean values when compared with patients without severe hypoglycaemia ($6.9\% \pm 1.0$ vs. $7.9\% \pm 1.2$; $F=5.7$, $p=0.01$). Patients with hypoglycaemic episodes rated their general health as being poorer compared with those without hypoglycaemia (57.7 ± 9.2 vs. 74.9 ± 3.2 ; $F=4.2$, $p=0.04$). No other differences were found regarding HRQOL.

Duration and age at onset of diabetes in relation to HRQOL

No significant correlations were found between duration of diabetes and different dimensions of HRQOL. The only significant difference between patients with an early onset (before puberty) compared with those with a later onset was in negative feelings (77.5 ± 3.2 vs. 62.6 ± 5.7 , $F=6.1$, $p=0.01$). That

Figure 3. Mean values and standard errors for HRQOL in diabetic patients with and without late complications



is, patients with an early onset of the disease experienced less negative feelings than patients who had their onset later in life. There were no differences in metabolic control between patients with early and late onset of diabetes.

Socio-economic factors and HRQOL

Education: Patients with less than 9 years in school had lower scores on the HRQOL with two exceptions: They had less negative feelings (non-significant) and were more satisfied with their family life than those with a higher education [87.5 (CI = $82.1-92.9$) vs. 78.6 (CI = $72.4-84.8$), $p=0.05$]. On the other hand, patients with lower education scored lower in their general health perceptions than patients with higher education (71.0 ± 4.3 vs. 80.2 ± 2.6 , $F=3.8$, $p=0.05$). There were no differences in metabolic control between the two groups.

Income: Low income earners scored lower on all parts of the HRQOL compared with patients with medium or high income. Significant differences among the three groups were found for physical functioning (75.0 ± 3.7 for low income vs. 92.1 ± 1.8 for high income; $F=9.3$, $p=0.0002$) mobility (88.6 ± 3.8 vs. 100.0 ± 0 ; $F=4.6$, $p=0.01$) and satisfaction with physical functioning (57.7 ± 4.8 vs. 71.2 ± 3.8 ; $F=3.2$, $p=0.04$). Low income earners experienced more limitations due to physical health (77.0 ± 4.7 vs. 95.2 ± 2.2 ; $F=4.7$, $p=0.01$). They also experienced more pain (68.2 ± 6.0 vs. 95.3 ± 2.8 ; $F=5.0$, $p=0.008$), less positive feelings (64.8 ± 3.7 vs. 74.8 ± 3.7 ; $F=4.1$, $p=0.01$), a declining sexual functioning (74.8 ± 5.3 vs. 83.4 ± 5.3 ; $F=2.8$, $p=0.006$) and rated their general health as being poorer compared with high income earners (69.2 ± 3.9 vs. 80.7 ± 4.5 ; $F=3.7$, $p=0.02$). There were no differences in metabolic control among the three groups. The mean values for HbA1c for low, medium and high income earners were $7.6\% \pm 1.3$; $7.6\% \pm 1.2$ and $7.4\% \pm 1.0$ respectively.

Cohabitation: The only significant difference between those who lived with a partner and those who lived alone was in the emotional factor. Those living with a partner scored significantly higher on positive feel-

ings than those living alone (75.0 ± 2.2 vs. 63.2 ± 5.0 , $F=6.3$, $p=0.01$). Patients living together with a partner had a somewhat lower HbA1c mean value ($7.5\% \pm 1.1$ vs. $7.9\% \pm 1.4$). This difference, however, was not significant.

Daily work: Manual workers scored lower on physical functioning (78.9 ± 3.7 vs. 87.0 ± 2.3 ; $F=3.7$, $p=0.05$) satisfaction with physical health (56.1 ± 4.9 vs. 71.2 ± 3.2 ; $F=6.7$, $p=0.01$), and general health perceptions (69.9 ± 4.1 vs. 81.2 ± 2.6 ; $F=6.0$, $p=0.01$), but were more satisfied with their family life (87.9 ± 2.3 vs. 77.6 ± 3.4 ; $F=5.6$, $p=0.01$) when compared with employees. There were no significant differences in metabolic control between the two groups.

Age, gender and HRQOL

Age was found to be slightly correlated with pain ($r=0.20$) and sexual functioning ($r=-0.20$). These results suggest that older patients experience more pain and a lower sexual functioning.

The only difference in HRQOL between males and females was that males experienced less pain than females (84.1 ± 4.1 vs. 70.5 ± 5.3 ; $F=4.1$, $p=0.05$). Males

Table 4. Factors explaining the variance in different aspects of health-related quality of life. Results from stepwise regression analyses in patients with poor metabolic control

Dimensions of HRQOL/Explanatory factors	R	R ²	β	SE (B)
Physical functioning				
Step 1. HbA1c	0.60	0.30	-19.8	7.4
Mobility				
Step 1. HbA1c	0.70	0.50	-29	7.0
Satisfaction with physical health				
Step 1. HbA1c	0.60	0.40	-31.5	9.7
Step 2. HbA1c and education	0.70	0.60	28.0	11.9
Limitations in physical functioning				
Step 1. Age at onset	0.60	0.40	-1.5	0.5
Step 1. Age at onset and working conditions	0.70	0.50	21.2	8.5
Step 1. Age at onset, working conditions and cohabitation	0.80	0.60	30.1	8.6
Positive feelings				
Step 1. Age at onset	0.50	0.20	-1.4	0.60
Sleeping problems				
Step 1. Retinopathy	0.50	0.20	23.7	10.7
General health perceptions				
Step 1. Neuropathy	0.50	0.30	29.6	12.4
Family functioning				
Step 1. HbA1c	0.60	0.40	-20.6	7.3
Sexual functioning				
Step 1. Neuropathy	0.60	0.40	38.6	14.3
Step 2. Neuropathy and income	0.80	0.60	22.2	10.0

had a slightly better metabolic control than females (7.4% vs. 7.8%), though this difference was not statistically significant.

Factors explaining variance in HRQOL

Table 4 shows factors important for different dimensions of health-related quality of life. In stepwise regression analysis in the group of patients with unacceptable metabolic control it was found that the most important factor for physical characteristics of health-related quality of life was HbA1c (metabolic control). It explained 30% of the variance in physical functioning, 50% in mobility, 40% in satisfaction with physical health and 40% in satisfaction with family life. Further, 30% of the variance in general health perception and 40% of the variance in sexual functioning was explained by the presence of neuropathy (Table 4).

Discussion

In this study we found that patients with poor metabolic control showed a poorer quality of life when compared with patients with acceptable metabolic control. However, when comparing the whole group of diabetic patients with the general population there were no significant differences in HRQOL. Thus the group of diabetic patients as a whole does not differ much from the general population. It appears that a chronic disease with a treatment that compensates for the deficiency need not affect HRQOL, if the treatment is reasonably adequate and adapted to the patient's daily life activities. In the last 10 years, routine care in our group of patients has been similar to the intervention groups in the DCCT¹¹ and the SDIS studies.⁹ In the current study, patients with acceptable metabolic control were those with the highest ratings on HRQOL, and their number of late complications were low compared to patients with poor control. The latter showed the lowest ratings on HRQOL scales, which indicates that, if the treatment is non-adequate, the patient's quality of life is affected by physical symptoms and by the presence of late complications. On the other hand, if the treatment regime is too tight, the patient's quality of life might also deteriorate. Patients with a tight control and who had experienced hypoglycaemic episodes that they could not manage on their own rated their general health as being poorer than those without severe hypoglycaemia. Previously, HRQOL measures in two cohorts of diabetic patients have shown that

patients with tight glycaemic control had lower ratings.⁴ These authors found an 'inverted U' relationship between level of metabolic control and patients' reports on health status. The same inverted U-pattern was also observed in patients in the current study, but not to the same extent that we found in an earlier study on the same group of patients.³ The special attention paid to this group of patients might have biased the results. With reference to knowledge of diabetes, the investigated patient group might be considered as a selected group in that these patients have been followed for 10 years.

There was an expected relation between the presence of late complications, poorer metabolic control and lower ratings for physical health, sexual functioning, positive feelings and general health perceptions. These patients, with late complications also experienced more pain than patients who had completely escaped complications over the long observation period. This finding is in line with most other studies of late complications and well-being.^{2,13,14,17}

Parkerson *et al.*¹³ have suggested that neither the duration of diabetes nor the intensity of insulin treatment affects HRQOL. They found non-diabetic factors, such as marital status and social relationships more important. The same appears to be the case in our study, in that the duration of diabetes did not affect the HRQOL. We found, however, that patients with early onset of diabetes had less negative feelings when compared to those who contract diabetes later in life. Hanestad¹⁸ found that living alone had a negative effect on quality of life. In our study we too found that patients who lived together with a partner had higher ratings on positive feelings than patients who lived alone. However, we did not find a similar difference in the case of negative feelings.

The Pittsburgh Epidemiology of Diabetes Complications (EDC) Study¹⁹ found that more educated and wealthier patients had a better metabolic control than patients with low income and low education. The present findings corroborate their data. Although patients with low education had lower scores on most variables, they were more satisfied with their family life. Low income was associated with lower scores of physical functioning, mobility and satisfaction with physical health. Differences were found between manual workers and employees, with manual workers being less satisfied with their physical functioning and their general health but more satisfied with their family life. The majority of patients with low education were manual workers.

The diabetes care team is probably of primary importance for the quality of life of diabetic patients. The care team must not be solely interested in

improving the patients' metabolic control and focus too much on the purely medical aspects of diabetes. Nerenz *et al.*²⁰ compared physicians' and patients' own ratings of patient health status and found that physicians rated the patients' general health significantly higher than the patients themselves. Studies on attitudes toward diabetes management in members of the care team showed that the physician views himself and not the patient as the primary decision maker.²¹ Modern diabetes care has to focus on both an increase in the patients' quality of life and on improving the metabolic control. Measurements of quality of life in diabetic patients, like SWEDQUAL, might serve a useful purpose. The present study showed that efforts to obtain good metabolic control might also be beneficial regarding quality of life. After many years of unsatisfactory metabolic control, patients with complications suffered an impaired quality of life. The present findings also indicate that in the long run satisfactory metabolic control might protect diabetic patients from an impaired quality of life.

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