

## The impact of type 2 diabetes mellitus on daily functioning

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**Background.** Traditionally, health and the outcomes of medical treatment have been measured in terms of morbidity, incidence or prevalence of disease, or even mortality. This disease model provides an adequate framework for acute illnesses, but for chronic diseases, severity and their effect on everyday functioning are paramount. For chronic diseases, functional health status, as a vital part of quality of life, is now recognized as an important outcome measure of the GP's care.

**Objective.** We aimed to assess the impact of type 2 diabetes mellitus on functional health status in Dutch general practice.

**Method.** We conducted a cross-sectional study of the functional health status of all patients with type 2 diabetes mellitus under 85 in two general practices, using the Sickness Impact Profile (SIP) and the COOP/WONCA charts. A control group of non-diabetic patients was selected, matched for practice, sex and age.

**Results.** In total, 127 type 2 diabetes mellitus patients and 127 controls participated in the study, the responses being 78 and 70%, respectively. Between these groups the following were significantly different: the SIP subscore Physical, the SIP sum score and the COOP/WONCA scores for physical fitness and overall health. Type 2 diabetes mellitus patients were 2.46 (95% CI 1.5–4.1) times more likely to experience functional impairment. Cardiovascular morbidity (odds ratio 2.5, 95% CI 1.3–4.7), locomotory morbidity (odds ratio 2.6, 95% CI 1.4–5.1) and diabetes itself (odds ratio 1.4, 95% CI 1.1–1.9) were significantly associated with the presence of functional impairment.

**Conclusion.** This study demonstrates the impact of type 2 diabetes mellitus on functional status, particularly in relation to cardiovascular morbidity.

**Keywords.** General practice, health status indicators, primary health care, type 2 diabetes mellitus.

### Introduction

Type 2 diabetes (non-insulin-dependent) mellitus is one of the most complicated diseases managed in primary care.<sup>1,2</sup> Standards have been developed to establish uniform care.<sup>3–5</sup> Strict metabolic control is recommended although it is still unclear whether this prevents premature mortality<sup>6,7</sup> and improves 'quality of life'.<sup>8–10</sup>

However, strict metabolic control is difficult to achieve and even if strict metabolic control is reached and objective markers of disease are improved, it may adversely affect 'quality of life' as a consequence of therapeutic side-effects.<sup>11</sup> Therefore, 'quality of life' has to be an important factor in the evaluation of care. As one of the aspects of 'quality of life', the concept of functional health status has been defined: the impact of disease on an individual's daily functioning.<sup>12</sup> As functional health status reflects the patient's capacities rather than the activity of the disease, the instruments to assess functional health status are not disease specific but generic in concept. One of the difficulties in interpreting and understanding functional health status is the role of co-morbidity, which constitutes a particular

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problem in type 2 diabetes mellitus patients and interferes with the impact of diabetes itself on functional health status.

Although many studies have described the high prevalence of complications and morbidity in type 2 diabetes mellitus patients, very few data concerning the impact of type 2 diabetes mellitus on the functional health status of patients are available. Data suggest that patients with diabetes experience a decrease in their 'quality of life' compared with healthy individuals and that functional health status decreases as complications become more severe.<sup>13–16</sup> The aim of this study was to assess the impact of type 2 diabetes mellitus on the functional health status in Dutch general practice.

## Patients and methods

### *Setting*

The study was performed in two general practices (six GPs, 11 500 patients) taking part in the Nijmegen Monitoring Project of the Department of General Practice and Social Medicine of the University of Nijmegen.<sup>17</sup> This project supervises the management of patients with chronic diseases in primary care. Type 2 diabetes mellitus patients are included when the diagnosis is in agreement with the WHO criteria.<sup>18</sup> Patients who are treated with insulin within 1 year of diagnosis and who remain on it are regarded as type 1 diabetes mellitus patients (insulin-dependent); all others are considered as having type 2 diabetes mellitus.

The management of diabetes mellitus in the Nijmegen Monitoring Project is based on the guidelines of the Dutch College of General Practitioners.<sup>5</sup> The GP is provided with computer-assisted feedback on adherence to follow-up care, key clinical data on outcome of care and adherence to the management guidelines.<sup>19</sup>

### *Patients*

All type 2 diabetes mellitus patients aged under 85 years were invited to take part in the study. Patients were excluded when their GP had established major additional life-threatening morbidity or considered them unsuitable for participation on account of psychosocial reasons. A control group of non-diabetic patients was selected and matched for practice, sex and age. In all controls, blood glucose was measured. Controls with a blood glucose value in the diabetic range were excluded.<sup>18</sup>

### *Data on co-morbidity*

The GP provided data from the records of both type 2 diabetes mellitus patients and controls on the presence of co-morbidity, according to the definitions of the International Classification of Health Problems in Primary Care (ICHPPC).<sup>20</sup> This co-morbidity was categorized in seven groups: (1) cardiovascular (myocardial infarction, angina pectoris, heart failure, peripheral vascular disease,

transient ischaemic attack, cerebrovascular accident); (2) hypertension; (3) locomotory morbidity (rheumatoid arthritis, osteoarthritis of the hip, knee and lumbar spine, and back pain with radiating symptoms); (4) psychosocial problems (depression, anxiety, bereavement); (5) eye diseases (cataract, retinopathy); (6) cancer; and (7) pulmonary morbidity (asthma, COPD).

### *Data on functional health status*

Two generic instruments were selected to measure functional health status: the Sickness Impact Profile (SIP) and the COOP/WONCA charts.<sup>21–23</sup> No disease-specific instrument was included owing to the nature of this study being a comparison of type 2 diabetes mellitus patients and controls. For both instruments Dutch validated versions were available.<sup>23,24</sup>

The SIP consists of 136 questions on daily functioning in relation to health and illness. These questions are grouped into 12 different categories. The list covers the domains of physical function (categories: body care/movement, mobility, ambulation), psychosocial function (categories: emotional behaviour, social interaction, alertness behaviour, communication) and 'other' functions (categories: sleep and rest, home management, work, recreation/pastimes and eating). The calculation of the SIP-scores is described in detail elsewhere.<sup>21</sup>

The Dartmouth COOP functional status assessment charts/WONCA (COOP/WONCA) assess six domains of functional health: physical activities, feelings, daily activities, social activities, change in health and overall health. Each domain is covered by a single question to be answered on a five-point scale and is supported by a pictograph representing the options. The scores are calculated for each chart separately.

The SIP was completed by interview and the COOP/WONCA charts were given for self-completion.

### *Analysis*

Differences between type 2 diabetes patients, participants and nonparticipants, and controls with respect to socio-demographic variables, co-morbidity and clinical features were evaluated using the chi-square test and two-sample *t*-tests. The main aim of the analysis was to compare patients and controls for each of the categories separately for their SIP and COOP/WONCA scores. A difference in the SIP total score of 2 is considered as clinically relevant.<sup>24</sup> Data from a study of Jacobs with the Dutch version of the SIP ( $n = 973$ ) showed a standard deviation of 6.3.<sup>25</sup> If a similar standard deviation (SD = 6) was observed in this study, 142 patients and controls would be required to detect a difference of 2 on the SIP total score, with 80% power at the 5% significance level. Calculations for statistical significance for the SIP and COOP/WONCA scores used the two-sample *t*-test and for correlation the Spearman's rank test.

Owing to the highly skewed distribution of the SIP sum scores, a dichotomous cut-off point, used previously

TABLE 1 Clinical features of type 2 diabetes mellitus patients and controls

Clinical features	Type 2 diabetes mellitus ( <i>n</i> = 127)	Controls ( <i>n</i> = 127)
Mean age (years)	64.7 (10.2)	63.6 (11.1)
Sex men/women	35/65	35/65
Body-mass Index men (kg/m <sup>2</sup> )	28.4 (5.9)	25.5 (3.3) <sup>a</sup>
Body-mass Index women (kg/m <sup>2</sup> )	29.6 (4.7)	27.1 (3.9) <sup>a</sup>
Cardiovascular morbidity	33	17 <sup>a</sup>
Hypertension	21	15
Locomotory morbidity	23	24
Psychosocial morbidity	11	11
Eye diseases	23	4 <sup>a</sup>
Cancer	0.8	0.8
Pulmonary morbidity	6	5
Duration diabetes (years)	7.3 (6.2)	
Therapy		
Diet /oral /insulin	26 /62 /12	
Blood glucose at the time of interview, mmol l <sup>-1</sup>	8.6 (2.4)	
Blood glucose control last year <sup>b</sup>		
Good	29.1	
Moderate	37.6	
Poor	33.3	

Results are given as percentages, except mean age, Body-mass Index and duration of diabetes (standard deviation in parentheses).

<sup>a</sup>  $P < 0.01$ .

<sup>b</sup> Average of the fasting blood glucose measurements in the last year ( $n = 117$ , part of the patients were not controlled by their GP, so no average of the blood glucose could be calculated).

Good:	≤ 60 years: ≤ 6.9 mmol l <sup>-1</sup> ;	61–69 years: ≤ 7.9 mmol l <sup>-1</sup> ;	≤ 70 years ≤ 8.9 mmol l <sup>-1</sup>
Moderate:	≤ 60 years: 7.0–7.9 mmol l <sup>-1</sup> ;	61–69 years: 8.0–8.9 mmol l <sup>-1</sup> ;	≤ 70 years 9.0–10.9 mmol l <sup>-1</sup>
Poor:	≤ 60 years: ≤ 8.0 mmol l <sup>-1</sup> ;	61–69 years: 3 9.0 mmol l <sup>-1</sup> ;	≤ 70 years ≤ 11.0 mmol l <sup>-1</sup>

in the literature, was used to distinguish subjects with functional impairment (SIP sum score of 2% or higher) from subjects without functional impairment (SIP sum score less than 2%).<sup>13,24</sup> Odds ratios for functional impairment were obtained by means of the Mantel Haenszel procedure.

Multiple logistic regression analysis was used to estimate the impact of diabetes and the combined effect of having diabetes and other co-morbidity (see section data on co-morbidity) on functional health. The results of the logistic regression models were summarized using odds ratios with their 95% confidence intervals.

## Results

There were 181 type 2 diabetes mellitus patients aged under 85 years in the two practices (14 patients were over 85). Nineteen were excluded by their GP, so 162 patients were invited, of whom 127 participated in the study (response rate 78%). The mean age of non-participating type 2 diabetes mellitus patients was

significantly higher (69.3 versus 64.7 years,  $P = 0.01$ ), and they had significantly more cardiovascular co-morbidity (54 versus 33%,  $P = 0.02$ ) and hypertension (37 versus 21%,  $P = 0.05$ ) than participating type 2 diabetes mellitus patients. The mean blood glucose was significantly better in non-participating type 2 diabetes mellitus patients (7.5 versus 8.6 mmol l<sup>-1</sup>,  $P = 0.02$ ).

A control group ( $n = 181$ ) was matched for practice, age and sex. Fifty-four controls declined participation (response rate 70%). The clinical features of all type 2 diabetes mellitus patients and controls are summarized in Table 1. Type 2 diabetes mellitus patients had a significantly higher body-mass index ( $P = 0.005$ ), a higher prevalence of cardiovascular morbidity ( $P = 0.002$ ) and eye diseases ( $P = 0.001$ ) than controls. With the sample size ( $n = 127$  in both groups), a power of 76% at the 5% significance level could be reached to detect a difference of 2 (SD = 6) on the SIP total score. For all categories of the Sickness Impact Profile except Emotional Behaviour, patients had higher scores than controls (Table 2). For the categories of Body Care and Movement, Ambulation, Home Management, Work and Eating, the differences

TABLE 2 Mean Sickness Impact Profile scores<sup>a</sup>

Dimension	Category	Type 2 diabetes mellitus	Controls	<i>P</i> -value
Physical	Body care and movement	4.8 (8.7)	3.0 (5.4)	0.04
	Mobility	3.5 (7.1)	3.0 (7.1)	0.5
	Ambulation	11.0 (14.2)	7.3 (12.0)	0.02
Psychosocial	Emotional behaviour	3.3 (8.0)	3.6 (9.3)	0.7
	Social interaction	2.3 (3.9)	1.8 (4.6)	0.3
	Alertness behaviour	2.8 (9.8)	2.5 (10.3)	0.8
	Communication	3.8 (9.9)	2.2 (6.4)	0.1
Other categories	Sleep and rest	7.1 (12.9)	4.7 (10.5)	0.1
	Home management	12.5 (15.5)	7.7 (14.1)	0.01
	Work	13.7 (26.7)	6.0 (18.2)	0.0007
	Recreation/pastimes	10.0 (14.3)	7.7 (13.1)	0.1
	Eating	7.1 (3.8)	1.7 (3.4)	0.0001
	<b>SIP Physical</b>	5.6 (7.8)	3.7 (5.7)	0.02
	<b>SIP Psychosocial</b>	2.9 (5.0)	2.4 (5.6)	0.4
	<b>SIP total</b>	6.0 (6.2)	3.8 (5.7)	0.003

<sup>a</sup> Results are given as percentages of the total possible dysfunction (100%); the standard deviation is given in parentheses.

were statistically significant, resulting in a significant difference for the subscore 'physical' ( $P = 0.02$ ) and the sumscore 'SIP total' ( $P = 0.003$ ). Functional impairment (SIP sumscore of 2% or higher) was significantly more prevalent in the type 2 diabetes mellitus diabetic patients than in the controls (65 versus 43%,  $P = 0.0001$ ). Type 2 diabetes mellitus patients were 2.46 (95% CI 1.5–4.1) times more likely to experience functional impairment than were controls. After adjustment for cardiovascular morbidity the odds ratio was 2.18 (95% CI 1.3–3.7).

The COOP/WONCA scores for physical fitness and overall health were spread over the full range of the five-point score and were significantly different for patients and controls (Table 3). In contrast, patients and controls mostly scored 1 (excellent) and 2 (good) for the categories of feelings, daily activities and social activities. Most of the patients and controls (81 and 82%, respectively) indicated no changes of health during the preceding 2 weeks.

Among type 2 diabetes mellitus patients a higher mean SIP sum score was associated with increasing duration of diabetes ( $P = 0.02$ ,  $P$ -values based on Wilcoxon Rank Sums Scores) and the presence of cardiovascular morbidity ( $P = 0.05$ ). A higher SIP sum score was not, however, significantly ( $P = 0.5$ ) associated with poorer metabolic control. In controls, a higher SIP sum score was associated with increasing age ( $P = 0.001$ ), the presence of cardiovascular morbidity ( $P = 0.001$ ), locomotory morbidity ( $P = 0.0005$ ) and psychosocial morbidity ( $P = 0.02$ ).

Multiple logistic regression analysis, with the dichotomized SIP total score as the dependent variable,

showed that cardiovascular morbidity (odds ratio 2.5, 95% CI 1.3–4.7), diabetes itself (odds ratio 1.4, 95% CI 1.1–1.9) and locomotory morbidity (odds ratio 2.6, 95% CI 1.4–5.1) were significantly associated with the presence of functional impairment. Hypertension, psychosocial problems (depression, anxiety, bereavement), eye diseases (cataract, retinopathy) and pulmonary morbidity (asthma, COPD) were not significantly related to functional impairment.

Table 4 shows the Spearman's rank correlation coefficients between the SIP and the COOP/WONCA charts. Fair (0.46–0.63) correlations were found for the COOP/WONCA charts Physical fitness, Daily activities and Overall health, and the SIP sum score and the SIP subscore Physical. The correlations between the COOP/WONCA charts Feelings and Social activities and the SIP subscore Psychosocial scores were moderate (0.31–0.35). Testing these against zero, all Spearman's rank correlation coefficients reach the significance level ( $P < 0.01$ ).

## Discussion

In this controlled study we demonstrated the impact of type 2 diabetes mellitus on the patient's functional health status: the physical fitness of type 2 diabetes mellitus patients was clearly impaired. Functional health status decreased significantly with the presence of co-morbidity in particular cardiovascular co-morbidity and a longer duration of diabetes. Cardiovascular

TABLE 3 Distribution of scores on each of the six COOP/WONCA charts for type 2 diabetes mellitus patients (n = 127) and controls (n = 127)

Scores	% of subjects in any category <sup>a</sup>					Mean (SD)
	1	2	3	4	5	
Physical fitness: <sup>d</sup>						
Type 2 diabetes mellitus	9	7	26	38	20	3.53 (1.14) <sup>b</sup>
Controls	10	17	38	25	10	3.07 (1.11)
Feelings: <sup>e</sup>						
Type 2 diabetes mellitus	62	28	5	4	1	1.53 (0.83)
Controls	62	24	10	4	0	1.55 (0.83)
Daily activities: <sup>f</sup>						
Type 2 diabetes mellitus	62	28	5	4	1	1.77 (1.04)
Controls	53	26	15	5	1	1.76 (0.97)
Social activities: <sup>g</sup>						
Type 2 diabetes mellitus	85	10	2	2	1	1.25 (0.69)
Controls	84	10	3	2	1	1.26 (0.70)
Change in health: <sup>h</sup>						
Type 2 diabetes mellitus	5	7	81	6	1	2.90 (0.58)
Controls	5	6	82	6	1	2.91 (0.58)
Overall health: <sup>i</sup>						
Type 2 diabetes mellitus	12	8	49	30	1	3.00 (0.94) <sup>c</sup>
Controls	20	12	49	17	2	2.68 (1.02)

<sup>a</sup> Scores as percentage of subjects within any category of functional status: 1 = good, through to 5 = poor.

<sup>b</sup>  $P = 0.001$ .

<sup>c</sup>  $P = 0.01$ .

<sup>d</sup> Hardest physical activity that could be done for at least 2 minutes, from 'very heavy' to 'very light'.

<sup>e</sup> Extent of being bothered by emotional problems, from 'not at all' to 'extremely'.

<sup>f</sup> Extent of difficulties in doing usual activities, from 'no difficulty' to 'could not be done'.

<sup>g</sup> Extent to which social activity is limited by physical and emotional health, from 'not at all' to 'extremely'.

<sup>h</sup> Overall health compared with 2 weeks previously, from 'much better' to 'much worse' (3 = no change).

<sup>i</sup> General health, from 'excellent' to 'poor'.

TABLE 4 Rank correlations between dimensions of the Sickness Impact Profile and the categories of the COOP/WONCA charts

	COOP/WONCA charts				
	Physical fitness	Feelings	Daily activities	Social activities	Overall health
SIP Physical	0.63	0.19	0.54	0.29	0.46
SIP Psychosocial	0.37	0.31	0.50	0.35	0.49
SIP Sum score	0.57	0.23	0.60	0.31	0.56

co-morbidity turns out to be not only a predominant factor in the decreased life expectancy of type 2 diabetes mellitus patients: it impairs the patient's functional health status long before as well.<sup>26</sup>

In contrast, the scores on the psychosocial dimension were not negatively affected. Previous studies also suggest that the mental health of patients with diabetes did

not differ significantly from that of patients with other chronic conditions or from the general population.<sup>27,28</sup>

Although the SIP gives more detailed information, we found results in general comparable with the COOP/WONCA charts. First, both instruments indicate the impaired functional health of diabetic patients with regard to their physical fitness. However, the COOP/WONCA

chart daily activities showed no difference between type 2 diabetes mellitus patients and controls, although the SIP scores on home management, work, body care, and movement and ambulation were significantly different. Secondly, the SIP total score, which can be considered as a measure of overall health, was significantly different, as was the overall health score on the COOP/WONCA charts. Thirdly, the scores on the psychosocial dimensions were not significantly different for either the SIP or COOP/WONCA charts.

The SIP, a time-consuming research instrument, cannot be used in daily practice. In contrast, large-scale implementation of the COOP/WONCA charts seems feasible in general practice, and scores are immediately available. However, the COOP/WONCA charts are limited by their nature: each dimension of functional health is reduced to one single item. Nevertheless, when used routinely, the COOP/WONCA charts could provide a vocabulary for patient and GP to discuss functional health status.

We found four studies in which the functional health status of type 2 diabetes mellitus patients is compared with that of a control group.<sup>13,16,28,29</sup> Mitchell *et al.* measured the functional health of 393 type 2 diabetes mellitus diabetic patients and 486 controls using the SIP.<sup>13</sup> They found that 37% of the type 2 diabetes mellitus patients experienced functional impairment (SIP  $\geq$  2%). Our figures are higher: 64.5% of the patients and 42.5% of the controls had a SIP score  $\geq$  2%. However, all Mitchell's subjects were under 65 years of age (versus 50% in our study) and 54% of them were treated with a diet only (versus 25% in our study). In Mitchell's study, duration of diabetes, fasting blood glucose, hypertension, Body Mass Index and complications were significantly associated with the presence of functional impairment. Stewart *et al.* measured functional health and well-being of 9385 adults during consultations with 362 physicians by means of a 20-item general health survey (the MOS Short-Form General Health Survey, SF-20) used by both patients and physicians.<sup>28</sup> Patients with diabetes ( $n = 844$ , type 1 and type 2 diabetes mellitus) scored markedly worse on the domains of physical, role and social functioning. Mental health was not impaired. Ahroni *et al.* used the reference group of Stewart to compare diabetic patients ( $n = 577$ , 90% type 2 diabetes mellitus).<sup>29</sup> They found a larger decrease in all domains of functional status compared with Stewart. Those with a history of complications associated with diabetes had significantly more impairment than those without. Wändell *et al.* measured the functional health status of 229 diabetes mellitus diabetic patients aged 21–84 years (7% type 1, not shown separately), and 682 controls matched for sex and age from a standard population sample. He used the Swedish Health-Related Quality of Life Survey (SWEDQUAL), which instrument is adapted from the Medical Outcome Study (MOS). The most important independent predicting factors for health-related quality

of life were vascular and non-vascular co-morbidity. No significant correlations were found for duration of diabetes and HbA1c with the SWEDQUAL results.

Although in our study mean SIP scores increase with poorer metabolic control, a higher SIP sum score was not significantly associated with poorer metabolic control. Weinberger found no linear relationship between dimensions of functional health status and glycosylated haemoglobin levels, nor did he find any association between change in glycosylated haemoglobin levels and change in functional health.<sup>11</sup> However, three randomized prospective studies showed that improved metabolic control was associated with better 'quality of life'.<sup>8,10,30</sup>

The evidence we found for the decreased functional health status of diabetic patients may be underestimated. On the one hand, the study cohort was carefully diagnosed and treated for a long time in general practice. So, their current condition reflects their disease and not—in part—undertreatment or poor management. On the other hand, survival of the fittest patients over the years may have biased the cohort. Exclusion of frail patients by the GP may have added to this selection and the same is probably true for the refusal to take part: non-participants had more complicating co-morbidity than participants. If these less-fit patients were included, the scores for functional health would have indicated even more impairments.

Our results support the inclusion of functional health status measurement in research aimed at the evaluation of outcomes of care in type 2 diabetes mellitus patients. In daily practice, treatment of type 2 diabetes mellitus patients has to be based on guidelines but will also largely depend on individual conditions as the role of co-morbidity and the functional health status. The general agreement between SIP and COOP/WONCA charts, and the latter's feasibility for routine practice, may suggest that these charts could provide a short, but systematic, orientation on functional health.

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