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New Diabetes Questionnaire to add patients' perspectives to diabetes care for adults with type 1 and type 2 diabetes: nationwide cross-sectional study of construct validity assessing associations with generic health-related quality of life and clinical variables

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ABSTRACT

Objectives To study evidence for construct validity, the aim was to describe the outcome from the recently developed Diabetes Questionnaire, assess the associations of that outcome with clinical variables and generic health-related quality of life, and study the sensitivity to differences between clinically relevant groups of glycaemic control in adults with type 1 and type 2 diabetes in a nation-wide setting.

Design Cross-sectional survey.

Setting Swedish diabetes care clinics connected to the National Diabetes Register (NDR).

Participants Among 2479 adults with type 1 diabetes and 2469 with type 2 diabetes selected at random from the NDR, 1373 (55.4%) with type 1 and 1353 (54.8%) with type 2 diabetes chose to participate.

Outcome measures The Diabetes Questionnaire, the generic 36-item Short Form version 2 (SF-36v2) health survey and clinical variables.

Results Related to the prespecified assumptions, supporting evidence for construct validity for the Diabetes Questionnaire was found. Supporting divergent validity, the statistically significant correlations with the clinical variables were few and weak. In relation to the SF-36v2 and in support of convergent validity, the strongest correlations were seen in the Diabetes Questionnaire scales General Well-being and Mood and Energy. In those scales, machine learning analyses showed that about 40%–45% of the variance was explained by the SF-36v2 results and clinical variables. In multiple regression analyses among three groups with differing levels of glycated haemoglobin adjusted for demographics, other risk factors, and diabetes complications, the high-risk group had, in support of sensitivity to clinically relevant groups, statistically significant lower scores than the well-controlled group in most Diabetes Questionnaire scales.

Conclusions This nation-wide study shows that the Diabetes Questionnaire captures some generic health-related quality-of-life dimensions, in addition to adding diabetes-specific information not covered by the SF-36v2 and clinical variables. The Diabetes Questionnaire is also sensitive to differences between clinically relevant groups of glycaemic control.

Strengths and limitations of this study

- The cross-sectional study used a large, heterogeneous nationwide sample of adults with type 1 diabetes and adults with type 2 diabetes selected at random.
- Respondents were representative of the 2015 population in the Swedish National Diabetes Register.
- The Diabetes Questionnaire scales scores were related to relevant clinical variables and a well-known and often recommended measure of generic health-related quality of life.
- The analyses were limited to the respondents and might reflect a group with greater motivation for participation.
- The questionnaires were only offered in Swedish.

INTRODUCTION

Everyday life with diabetes as an adult is a complex challenge. Diabetes makes individuals responsible for self-management to avoid serious short-term and long-term complications, while balancing self-perceived health and well-being in the present as well as in the future.[1–6] To support skills for self-management is a central task of diabetes care, and the individual patient's prerequisites, wishes and available evidence must be taken into account.[1 4–6] An important step for the

Swedish National Diabetes Register (NDR) has therefore been to broaden healthcare provider perspectives and enable a systematic collection of adults' perspectives of living with diabetes and their experiences of whether they are offered adequate support from diabetes care.[7–10] The newly developed Diabetes Questionnaire is intended to support meetings with individuals and provide a means for quality improvement at the local, regional and national levels.[7–9]

The Diabetes Questionnaire was developed from interviews with adults with type 1 or type 2 diabetes that identified a broad range of aspects important to the target group, such as well-being, impact on daily life, capabilities to manage diabetes and support from diabetes care.[9] In line with Sen's capability approach,[11 12] the Diabetes Questionnaire focuses on the individual's opportunities, prerequisites and possible barriers to live a good life with diabetes.[7–9] Supporting evidence for content validity, face validity and ease of items understandability and answerability has been presented.[8 9] In addition, supporting evidence for test–retest reliability and that the scales can be used for comparison between men and women, between different age groups, and, for most scales, between type 1 and type 2 diabetes have been provided.[7 8] Furthermore, the scales can detect differences between clinically relevant subgroups, such as diabetes type, diabetes treatment, age group and gender.[7] We have also begun to study the associations with clinical variables by showing low individual-level correlations with glycated haemoglobin (HbA_{1c}), systolic blood pressure (SBP) and low-density lipoprotein (LDL) cholesterol.[7]

This study adds to previous work and reports on an extended analysis of the evidence for construct validity. Construct validity concerns the confidence that a questionnaire captures the construct it was intended to measure.[13] It is a measurement property that involves a complex process using a variety of techniques studying differences between relevant groups and prespecified assumptions of logical relationships to scores of a range of other measures and patient characteristics.[13 14] The assumptions can postulate which aspects are expected to be related to each other, presenting evidence for convergent validity, and which aspects are expected to be relatively unrelated, supporting evidence for divergent, also known as discriminant, validity.[13] For this work, we chose to focus on differences between subgroups of glycaemic control as measured by HbA_{1c} and the relations to clinical variables relevant for diabetes care and an often-recommended generic measure of health-related quality of life, the 36-item Short Form version 2 (SF-36v2) health survey. To study evidence for construct validity, the aim was to describe the outcome from the Diabetes Questionnaire, to assess the associations of that outcome with clinical variables and generic health-related quality of life, and to study the sensitivity to differences between clinically relevant groups of glycaemic control in adults with type 1 and type 2 diabetes in a nationwide setting.

METHODS

Sample and data-collection

In this cross-sectional survey, 2479 adults with type 1 diabetes and 2469 with type 2 diabetes were selected at random without replacement from the Swedish NDR. Eligibility criteria were being alive, 18–80 years of age, and recorded in the NDR during the period from 30 September 2014 to 1 October 2015 with at least one recorded test of HbA_{1c} level during the previous 12 months. With these criteria, 29 245 adults with type 1 diabetes at hospital outpatient clinics and 208 852 adults with type 2 diabetes at primary healthcare centres were eligible for recruitment. In the data collection phase, we aimed at a sample size allowing for subgroup analyses.

The Diabetes Questionnaire, the SF-36v2 survey, and a prepaid return envelope were sent by email in October 2015 to survey selectees and again to non-respondents after 30 days.[7 15] Both questionnaires were answered by 1373 (55.4%) individuals with type 1 diabetes and 1353 (54.8%) with type 2 diabetes.[15] With small differences in response rate depending on the questionnaires in question, the sample has been described as previously focusing on the scale development of the Diabetes Questionnaire[7] and separate analyses of the SF-36v2 data.[15] Age, sex and clinical variables (diabetes type defined by clinical diagnosis, diabetes duration, HbA_{1c} level, cardiovascular risk factors, complications, physical activity level and receipt of medical treatment) recorded because of their relevance to high-quality diabetes care were collected from the NDR.

Diabetes Questionnaire

The Diabetes Questionnaire is a 33-item self-reporting questionnaire having a total of 12 scales divided into two main parts.[7 8] Part 1 has 22 items on eight scales and acts as a patient-reported outcome measure (PROM). These scales are General Wellbeing (GenW), Mood and Energy (MoE), Free of Worries about blood sugar (FreW), Capabilities to Manage your Diabetes (ManD), Diet and Exercise (DiEx), Not Limited by Diabetes (NLD), Not Limited by Blood Sugar (NLBS) and Support from Others (SuO). Part 2 is an 11-item patient-reported experience measure (PREM) with four scales. Those scales are Support from Diabetes Care (SuDC), Access to Diabetes Care (AcDC), Continuity in Diabetes Care (CoDC) and Medical Devices and Medical Treatment (MDMT). All scales are scored from 0 to 100, with higher scores representing the more desirable outcome. The scales ManD, NLBS and MDMT are specific to diabetes type.[7]

SF-36v2 survey

The SF-36v2 survey is a self-reporting questionnaire for generic health-related quality of life with support for its validity and reliability in overall populations, such as people with diabetes.[3 16–20] We used the self-administered standard form in Swedish and software from QualityMetric. The eight domains produced are physical functioning (PF); role-physical, that is role limitations

due to physical health problems; bodily pain; general health (GH); vitality (VT); social functioning (SF); role-emotional, that is role limitations due to mental health problems; and mental health (MH). The domains are scored from 0 to 100. Higher scores indicate a better general health-related quality of life.[16 17]

Prespecified assumptions

As the Diabetes Questionnaire is intended to measure patient perspectives on how they feel, how their diabetes treatment is going and their experiences of support from diabetes care, the prespecified assumptions for correlations with clinical variables and the SF-36v2 were as follows:

- Based on clinical experience, it was proposed that, in support of divergent validity, a small number of negative and weak correlations would be found between the Diabetes Questionnaire scales and the clinical variables, mostly related to the HbA_{1c} level. There would be no correlations with SBP and LDL cholesterol.
- Based on examinations of the content in the two questionnaires, it was proposed that in support of convergent validity, the Diabetes Questionnaire PROM scales GenW, MoE, FreW, ManD, DiEx, NLD and NLBS would have more and stronger correlations to the SF-36v2 domains, as compared with the PROM scale SuO and the PREM scales (SuDC, AcDC, CoDC and MDMT). Observed correlations would be positive, with the strongest in GenW and MoE. In support of divergent validity strong correlations were not expected across the other scales. Correlations ≥0.60 were considered as very strong, 0.50 to <0.60 as strong, 0.40 to <0.50 as moderate and <0.40 as weak.

Statistical analysis

The data for participants with type 1 and type 2 diabetes were analysed separately. The descriptive statistics for each variable are based on non-missing observations. The continuous variables are given as means and SD for normal distributions and as medians and IQRs for skewed distributions. The categorical variables are presented as numbers and percentages. The generation of scale scores from the Diabetes Questionnaire is described in detail elsewhere.[7] The SF-36v2 domain scores were generated using the manual and licensed software from QualityMetric.[17]

In relation to the prespecified assumptions, Spearman's rank correlation was used to study the monoton associations between the Diabetes Questionnaire scale scores and the clinical variables age, diabetes duration, HbA_{1c} level, body mass index (BMI), LDL cholesterol and SBP, as well as between the scores from the Diabetes Questionnaire scales and the SF-36v2 domains. To broaden the analysis, machine learning using random forests was conducted to investigate non-linear associations between the Diabetes Questionnaire scales and the SF-36v2 domains together with clinical variables (age, sex, diabetes duration, HbA_{1c} level, BMI, LDL cholesterol and SBP). Random forest is a general tree-based regression and classification method that uses bootstrapping to create a large number of regressions of classification trees that are combined to produce a model prediction.[21] The use of a large number of trees allows the model to depict non-linear associations without the need to prespecify these in a model, while at the same time guarding against overfit.[21] First, the variance in all Diabetes Questionnaire scales was examined in relation to the SF-36v2 domains and the clinical variables together. Next, the variable importance of the SF-36v2 domains and the clinical variables as predictors of the PROM scales GenW and MoE were examined. We also examined the percent variance in HbA_{1c} explained by another clinical variable, the Diabetes Questionnaire scales, and the SF-36v2 domains together. The results are given as percent of the total variance. Each model contained 1000 trees.

To study the sensitivity of the Diabetes Questionnaire scales to clinically relevant groups of glycaemic control, group-level associations between the Diabetes Questionnaire scales and glycaemic control as measured by HbA_{1c}, unadjusted and adjusted multiple regression analyses were conducted in the same manner as previously described for the SF-36v2 data.[15] HbA_{1c} was considered as a categorical variable divided into three clinically relevant groups corresponding to differing levels of glycaemic control and consequently differing levels of the risk of diabetes complications according to international and Swedish treatment guidelines.[4 22] The three groups were well-controlled (<52 mmol/mol), sub-optimal (52–69 mmol/mol) and high-risk (≥70 mmol/mol). For the three HbA_{1c} groups, the least square mean estimates and 95% CIs were calculated for each scale. The scale observations were modelled with a linear model with fixed effects for the HbA_{1c} group (exposure), age, sex, diabetes duration, BMI, SBP, LDL-cholesterol, micro-albuminuria and macro-albuminuria, estimated glomerular filtration rate, retinopathy, smoking status, physical activity level, previous coronary heart disease, previous stroke, and receipt of antihypertensive and lipid lowering treatments. Missing data were imputed 10 times, using multiple chained equations. The analyses were performed separately for each imputed data set, and the results were subsequently combined using Rubin's rules. The results are presented as least square mean estimates with 95% CIs.

The extent of missing data was 0% for age and sex, 7.2% for clinical variables (range 0%–36.5%), 1.7% for the SF-36v2 domains (range 0%–3.3% for individual dimensions) and 4.8% for the Diabetes Questionnaire scales (range 0.3%–34.7% for individual scales). For the Diabetes Questionnaire, the higher extent of missing data is likely related to having 'not applicable' as a response alternative in some scales, which at this stage was treated as missing data. For scales without 'not applicable' as a response alternative, the range for missing data was 0.3%–2.8%.

The standardised mean difference was used to examine the data balance between the HbA_{1c} groups and the

deviation from the means in the clinical and demographic data. A significance level of 5% was used throughout; no allowance was made for multiplicity of statistical tests. The analyses were conducted using SAS V.9.4 and R V.3.4.4.

Patient and public involvement statement

The Diabetes Questionnaire was based on qualitative interviews with adults living with diabetes.[8 9] Adults with diabetes and representatives from patient organisations participated in expert reviews during the development and initial testing.[8] Adults with diabetes were involved in the pretesting phase by participating in cognitive interviews and being consulted to comment on questionnaire revisions.[8] The analyses presented here as the previous scale development and evaluation of reliability and validity relied on the contributions from those adults with diabetes who responded to the questionnaires.[7 8] The Swedish Diabetes Foundation, the national patient organisation, has expressed their support for the project.

RESULTS

Among respondents with type 1 diabetes, 50.3% were men. The averages of key statistics were 48.6 years for age, 24.7 years for diabetes duration, and 62 mmol/mol for HbA_{1c} level. Among respondents with type 2 diabetes, 60.8% were men. Corresponding averages were 66.6 years for age, 9.4 years for diabetes duration, and 53 mmol/mol for HbA_{1c} level (table 1). The crude means and SD for the Diabetes Questionnaire scales are given in online supplemental table S1. The clinical characteristics of non-respondents are given in online supplemental table S2.

The descriptive statistics are presented as the means and SD for normally distributed continuous variables, the median and IQR for skewed distributions, or number and percentages for categorical variables.

Monoton correlations related to the proposed assumptions between the Diabetes Questionnaire scale scores and the clinical variables

In line with the assumptions and in support for divergent validity, there were few statistically significant monoton correlations between the Diabetes Questionnaire scales and the clinical variables. Observed correlations were weak, and most were negative. The results are shown as heat maps in online supplemental figures S1,S2 with details provided in online supplemental tables S3 and S4.

As assumed, the HbA_{1c} level was the variable with most statistically significant correlations across the Diabetes Questionnaire scales. Statistically significant but weak correlations between having a lower and better HbA_{1c} level and higher and better scores were seen in several Diabetes Questionnaire scales. For participants with type 1 diabetes, significant weak negative correlations (−0.12 to −0.25) were seen in the five Diabetes Questionnaire PROM scales GenW, FreW, ManD, DiEx and NLBS. The strongest correlations were seen in ManD and DiEx. Among participants with type 2 diabetes, statistically significant but weak negative correlations (−0.13 to −0.24) were seen in the seven Diabetes Questionnaire PROM scales GenW, MoE, FreW, ManD, DiEx, NLD and NLBS and in the two PREM scales SuDC and AcDC. The strongest correlations were seen in MoE, FreW and ManD, with generally stronger correlations in the PROM scales than in the PREM scales online supplemental figure S1,S2 and tables S3,S4.

For age, statistically significant positive correlations showed that a higher age was weakly associated with higher and better scores in several Diabetes Questionnaire scales. For participants with type 1 diabetes, statistically significant weak positive correlations (0.11–0.19) were seen in the four PROM scales MoE, FreW, ManD and DiEx, and in the two PREM scales AcDC and MDMT. The highest correlations were seen in MoE, FreW and MDMT. Among participants with type 2 diabetes, statistically significant weak positive correlations (0.12–0.16) were seen in the six PROM scales GenW, MoE, FreW, ManD and DiEx. The highest correlations were seen in MoE, FreW and DiEx. For LDL cholesterol and SBP, the results came up to the expectations of no statistically significant correlations. However, for participants with type 1 diabetes, a statistically significant negative correlation showed that a lower SBP was weakly associated with better scores in MoE. A lower BMI showed statistically significant weak negative correlations with higher scores in DiEx in both diabetes types as with GenW and MoE in type 2 diabetes. For diabetes duration, statistically significant positive correlations showed that a longer duration was weakly associated with higher scores in FreW and ManD for participants with type 1 diabetes. For those with type 2 diabetes, statistically significant negative correlations showed that a longer duration was associated with lower scores in FreW and NLBS online supplemental figure S1,S2 and tables S3,S4.

Monoton correlations related to the proposed assumptions between scores in the Diabetes Questionnaire scales and the SF-36v2 domains

In line with the assumptions and in support for convergent validity, the statistically significant monoton correlations between the Diabetes Questionnaire scales and the SF-36v2 domains were stronger in seven of the PROM scales as compared with the PROM scale SuO and the PREM scales. As expected, the observed statistically significant correlations were all positive, showing an association between higher scores in both questionnaires. The results are shown in figures 1 and 2 and online supplemental tables S5 and S6.

As assumed, the strongest correlations were seen in the Diabetes Questionnaire PROM scales GenW and MoE. Statistically significant positive correlations showed that higher scores in GenW and MoE were strongly associated with higher scores in about half of the SF-36v2 domains. In GenW, statistically significant positive correlations were seen with the SF-36v2 domains PF, GH, VT and MH. The correlations were very strong with VT (0.60), strong with

Table 1 Clinical and demographic characteristics of the respondents separated by diabetes type and glycated haemoglobin (HbA_{1c}) level

	Type 1 diabetes					Type 2 diabetes				
Variable	All	HbA_{1c} <52 mmol/mol	HbA_{1c} 52–69 mmol/mol	HbA_{1c} ≥70 mmol/mol	Standardised mean difference, SMD	All	HbA_{1c} <52 mmol/mol	HbA_{1c} 52–69 mmol/mol	HbA_{1c} ≥70 mmol/mol	Standardised mean difference, SMD
Number (%)	1373	284 (20.7%)	781 (56.9%)	308 (22.4%)		1353	725 (53.6%)	503 (37.2%)	125(9.2%)	
Men, n (%)	690 (50.3)	152 (53.5)	391 (50.1)	147 (47.7)	0.077	822 (60.8)	444 (61.2)	302 (60.0)	76 (60.8)	0.016
Age, years (SD)	48.6 (16.4)	46.9 (17.0)	49.6 (16.1)	47.8 (16.3)	0.113	66.6 (9.1)	66.5 (9.1)	66.9 (9.0)	65.5 (9.7)	0.103
Diabetes duration, years (IQR)	22.0 (12.0–36.0)	19.0 (7.0–32.0)	23.0 (13.0–37.0)	24.0 (13.0–37.0)	0.150	8.0 (4.0–14.0)	6.0 (3.0–11.0)	10.0 (6.0–16.0)	13.0 (6.0–17.0)	0.443
HbA_{1c} mmol/mol (SD)	62 (12.7)					53 (12.5)				
BMI, kg/m^2 (SD)	26.0 (4.2)	25.2 (3.8)	26.0 (4.2)	26.7 (4.6)	0.239	29.9 (5.3)	29.3 (5.2)	30.3 (5.4)	32.0 (5.5)	0.332
Systolic blood pressure, mm Hg (SD)	127.0 (14.0)	124.8 (14.0)	127.5 (13.8)	127.8 (14.2)	0.145	134.3 (14.3)	134.0 (14.4)	134.5 (13.7)	135.1 (16.5)	0.046
Antihypertensive medication, n (%)	589 (44.7)	99 (36.9)	341 (45.3)	149 (50.2)	0.179	1070 (80.1)	572 (79.6)	404 (81.9)	94 (76.4)	0.091
LDL-cholesterol, mmol/L (SD)	2.4 (0.8)	2.5 (0.8)	2.4 (0.8)	2.5 (0.8)	0.077	2.5 (0.9)	2.5 (0.9)	2.4 (0.9)	2.5 (1.0)	0.026
Lipid-lowering medication, n (%)	642 (48.4)	94 (34.6)	378 (49.8)	170 (57.6)	0.315	900 (68.1)	472 (66.6)	344 (70.1)	84 (69.4)	0.050
Micro-albuminuria, n (%)	132 (10.3)	12 (4.6)	70 (9.5)	50 (17.6)	0.285	194 (18.0)	80 (13.9)	83 (20.1)	31 (34.1)	0.323
Macro-albuminuria, n (%)	31 (2.6)	5 (2.1)	12 (1.8)	14 (5.2)	0.126	52 (5.0)	27 (4.8)	20 (5.1)	5 (6.1)	0.037
Estimated glomerular filtration rate, mL/min (SD)	90.0 (23.5)	90.6 (20.7)	89.1 (22.6)	91.6 (27.7)	0.071	82.3 (23.5)	82.5 (22.3)	81.9 (24.0)	83.4 (27.9)	0.038
Retinopathy, n (%)	875 (65.9)	137 (50.6)	520 (68.2)	218 (74.1)	0.333	327 (29.4)	128 (21.7)	153 (36.3)	46 (47.0)	0.366
Coronary heart disease, n (%)	83 (6.3)	9 (3.3)	53 (7.0)	21 (7.1)	0.113	279 (22.4)	136 (20.2)	111 (24.0)	32 (28.6)	0.130
Stroke, n (%)	48 (3.6)	5 (1.9)	32 (4.2)	11 (3.7)	0.093	96 (7.8)	48 (7.2)	40 (8.9)	8 (7.1)	0.043
Smoker, n (%)	135 (10.1)	14 (5.1)	78 (10.2)	43 (14.4)	0.214	162 (12.9)	79 (11.7)	58 (12.3)	25 (23.1)	0.203
Physical activity, daily, n (%)	359 (27.6)	90 (33.5)	203 (27.2)	66 (23.2)	0.334	426 (34.9)	251 (38.7)	157 (33.9)	18 (16.7)	0.410
Diabetes treatment					0.136					0.813
Diet alone, n (%)						195 (14.4)	172 (23.7)	19 (3.8)	4 (3.3)	
Oral hypoglycaemic agent alone, n (%)						718 (53.1)	419 (57.8)	261 (52.0)	38 (30.9)	
Insulin alone, n (%)	1335 (97.2)	271 (95.4)	764 (97.8)	300 (97.4)		130 (9.6)	46 (6.3)	63 (12.5)	21 (17.1)	
Insulin and oral agent, n (%)	32 (2.3)	9 (3.2)	15 (1.9)	8 (2.6)		266 (19.7)	76 (10.5)	140 (27.9)	50 (40.7)	
Insulin pump users, n (%)	356 (26.2)	66 (23.8)	221 (28.5)	69 (22.5)	0.091	2 (0.5)	1 (0.9)	1 (0.5)	0 (0.0)	0.093

BMI, body mass index; LDL, low-density lipoprotein.

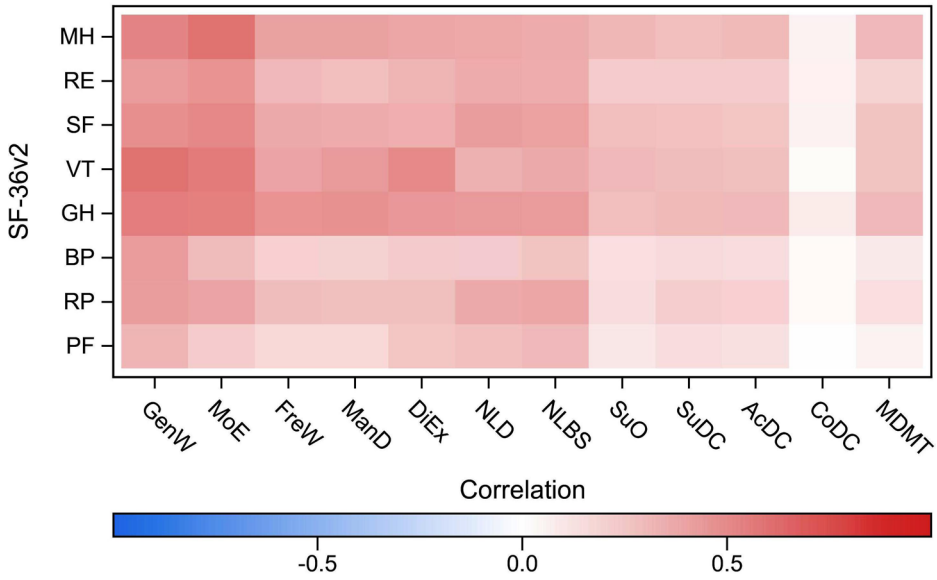

Figure 1 Spearman's rank correlation between the Diabetes Questionnaire scales and the SF-36v2 domains in type 1 diabetes. Diabetes Questionnaire scales: AcDC, Access to Diabetes Care; CoDC, Continuity in Diabetes Care; DiEx, Diet and Exercise; FreW, Free of Worries about blood sugar; GenW, General Wellbeing; ManD, Capabilities to Manage your Diabetes; MDMT, Medical Devices and Medical Treatment; MoE, Mood and Energy; NLBS, Not Limited by Blood Sugar; NLD, Not Limited by Diabetes; SuDC, Support from Diabetes Care; SuO, Support from Others. SF-36v2 domains: BP, bodily pain; GH, general health; MH, mental health; PF, physical functioning; RE, role-emotional; RP, role-physical; SF, social functioning; VT, vitality. SF-36v2, 36-item Short Form version 2.

GH and MH (0.51–0.56) and weak with PF. Among those with type 2 diabetes, there were also statistically significant strong positive correlations between GenW and SF (0.51). In MoE, statistically significant positive correlations were seen with the SF-36v2 domains GH, VT, SF and MH. The correlations were very strong with MH (0.60) and strong with GH, VT and SF (0.51–0.58). Among those with type 2 diabetes, statistically significant strong positive correlations were also seen between MoE and RF (0.51). For both diabetes types, statistically significant strong positive correlations were also seen between the PROM scale DiEx and the VT domain (0.51). Statistically significant

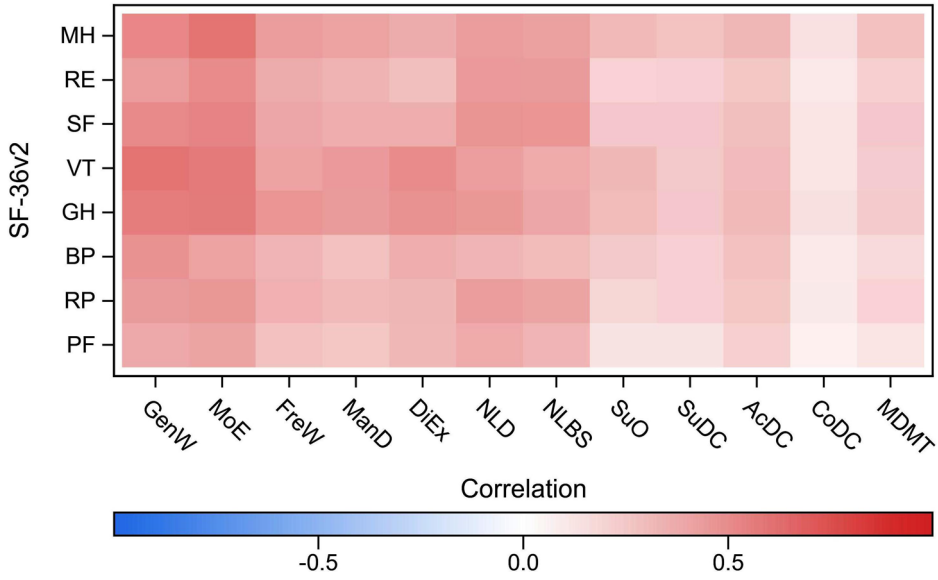

Figure 2 Spearman's rank correlation between the Diabetes Questionnaire scales and the SF-36v2 domains in type 2 diabetes. Diabetes Questionnaire scales: AcDC, Access to Diabetes Care; CoDC, Continuity in Diabetes Care; DiEx, Diet and Exercise; FreW, Free of Worries about blood sugar; GenW, General Wellbeing; ManD, Capabilities to Manage your Diabetes; MDMT, Medical Devices and Medical Treatment; MoE, Mood and Energy; NLBS, Not Limited by Blood Sugar; NLD, Not Limited by Diabetes; SuDC, Support from Diabetes Care; SuO, Support from Others. SF-36v2 domains: BP, bodily pain; GH, general health; MH, mental health; PF, physical functioning; RE, role-emotional; RP, role-physical; SF, social functioning; VT, vitality. SF-36v2, 36-item Short Form version 2.

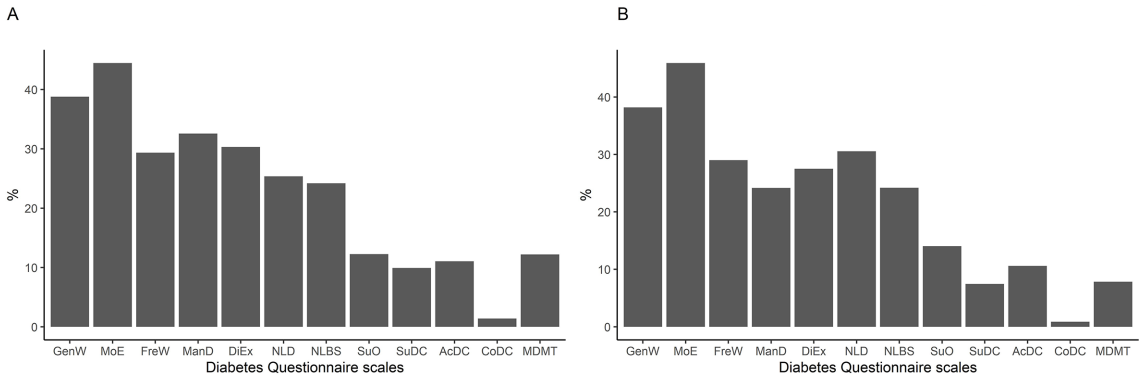

Figure 3 Per cent variance in the diabetes questionnaire scales explained by the SF-36v2 domains and clinical variables in type 1 (A) and type 2 diabetes (B). AcDC, Access to Diabetes Care; CoDC, Continuity in Diabetes Care; DiEx, Diet and Exercise; FreW, Free of Worries about blood sugar; GenW, General Wellbeing; ManD, Capabilities to Manage your Diabetes; MDMT: Medical Devices and Medical Treatment; MoE, Mood and Energy; NLBS, Not Limited by Blood Sugar; NLD, Not Limited by Diabetes; SF-36v2, 36-item Short Form version 2; SuDC: Support from Diabetes Care; SuO, Support from Others.

moderate positive correlations were also seen between the PROM scales and SF-36v2 domains. In NLD and NLBS, statistically significant moderate positive correlations were more common in type 2 diabetes than in type 1 diabetes. In support for divergent validity, the PROM scale SuO and the PREM scales, statistically significant correlations were weak (0.11–0.32) or absent (figures 1 and 2, online supplemental tables S5 and S6.

Non-linear associations to clinical variables and SF-36v2 domains together

The results from the machine learning analysis are shown in figure 3 and online supplemental figure S3. Similar results were seen for type 1 and type 2 diabetes. Among the PROM scales, the variance was explained by the SF-36v2 domains together with the clinical variables to almost 40% in GenW and to around 45% in MoE. In FreW, ManD, DiEx, NLD and NLBS, the variance was explained to about 25%–30% and in SuO to about 10%. Among the PREM scales, SuDC, AcDC and MDMT were explained to about 10% or below. In CoDC, almost no variance was explained (figure 3). As predictors of the Diabetes Questionnaire PROM scales GenW and MoE, the variables with the highest importance were the SF-36v2 domains GH, VT and MH. LDL cholesterol and SBP had low variable importance (online supplemental figure S3). The per cent variance in HbA_{1c} explained by other clinical variables, the SF-36v2 domains, and the Diabetes Questionnaire scales together was low, around 5% in type 1 diabetes and around 10% in type 2 diabetes. Consequently, the importance of the other clinical variables, the SF-36v2 domains, and the Diabetes Questionnaire scales as predictors of HbA_{1c} was not examined.

Sensitivity of the Diabetes Questionnaire scales to clinically relevant groups of glycaemic control

The results from the adjusted regression analyses of the Diabetes Questionnaire scales and the HbA_{1c} groups are presented separately for participants with type 1 and type 2 diabetes in figure 4. The least square mean estimates and CIs from the unadjusted and adjusted analyses are given detail in online supplemental table S7.

Among those with type 1 diabetes, the adjusted analysis of the HbA_{1c} groups showed significantly lower scores for the high-risk group than the well-controlled group in the eight PROM scales GenW, MoE, FreW, ManD, DiEx, NLD, NLBS and SuO as in the PREM scale SuDC. The largest between-group differences were seen in the PROM scales ManD and DiEx, where the well-controlled group had the significantly highest means, followed by the suboptimal group and the high-risk group. Among those with type 2 diabetes, the adjusted analysis showed that the high-risk group had significantly lower scores than the well-controlled group in all scales but CoDC. In the five PROM scales MoE, FreW, ManD, NLD and NLBS, the well-controlled group had the significantly highest means, followed by the suboptimal and high-risk groups. The largest between-group differences were seen in MoE, FreW, NLD and NLBS (figure 4, online supplemental table S7).

DISCUSSION

From a nationwide setting with a large sample of adults with type 1 and type 2 diabetes selected at random, we present the outcome from the Diabetes Questionnaire. To study construct validity, we assess convergent and divergent associations of that outcome with clinical variables and generic health-related quality of life, as measured by the SF-36v2 and assess the sensitivity to differences between clinically relevant groups of glycaemic control. We found supporting evidence for construct validity in both type 1 and type 2 diabetes. As expected, and in support for divergent validity, there were few statistically significant correlations with the clinical variables. The observed correlations were weak, and most were negative. Also as expected, and in support for convergent validity, the correlations with the SF-36v2 domains were positive; the strongest correlations were found in the

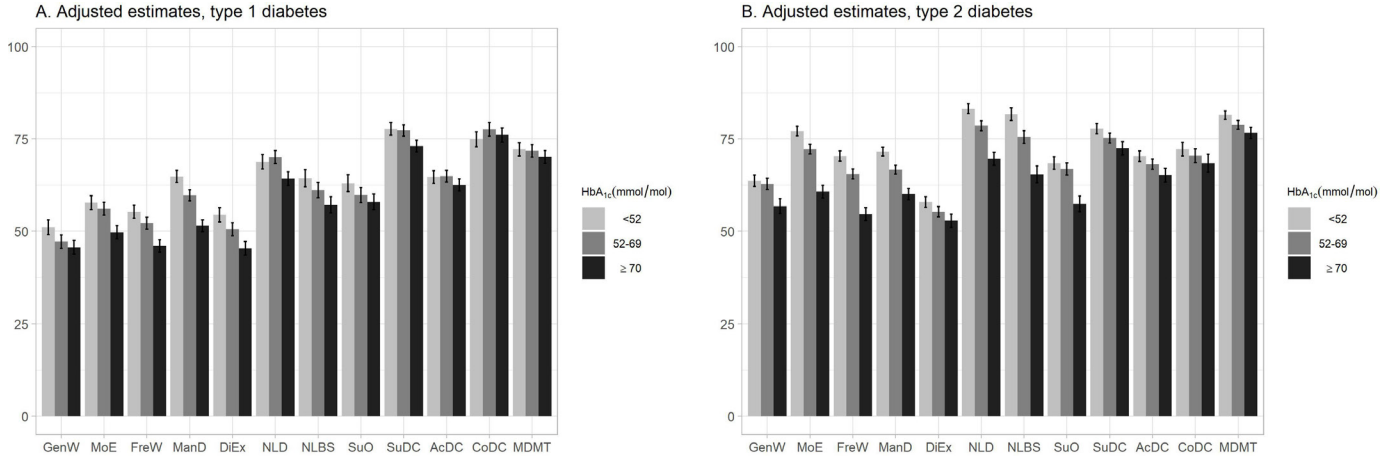

Figure 4 Adjusted least square mean estimates with 95% CIs for the Diabetes Questionnaire scales in type 1 diabetes (A) and type 2 diabetes (B) separated by glycated haemoglobin (HbA_{1c}) level. Adjusted for age, sex, diabetes duration, body mass index, systolic blood pressure, LDL cholesterol level, micro-albuminuria and macro-albuminuria, estimated glomerular filtration rate, retinopathy, smoking status, physical activity level, receipt of antihypertensive and lipid lowering treatments, previous coronary heart disease and previous stroke. AcDC, Access to Diabetes Care; CoDC, Continuity in Diabetes Care; DiEx, Diet and Exercise; FreW, Free of Worries about blood sugar; GenW, General Wellbeing; LDL, low-density lipoprotein ; ManD, Capabilities to Manage your Diabetes; MDMT, Medical Devices and Medical Treatment; MoE, Mood and Energy; NLBS, Not Limited by Blood Sugar; NLD, Not Limited by Diabetes; SuDC, Support from Diabetes Care; SuO, Support from Others.

Diabetes Questionnaire PROM scales GenW and MoE. Furthermore, either weak or no correlations were seen in the PREM scales, supporting divergent validity. In machine learning analyses, the SF-36v2 domains and the clinical variables together explained the variance in the PROM scales GenW and MoE to about 40%–45%. In the other scales, the variance explained was low. In regression analyses among three groups with differing levels of HbA_{1c} adjusted for demographics, other risk factors, and diabetes complications, the high-risk group had, in support of sensitivity to clinically relevant groups of glycaemic control, statistically significantly lower scores than the well-controlled group in most Diabetes Questionnaire scales for participants with type 1 diabetes and in almost all scales for those with type 2 diabetes. Statistically significant differences between all three groups of glycaemic control were seen in two scales for type 1 diabetes and in five scales for type 2 diabetes.

Findings and implications

Evaluating the measurement qualities of a questionnaire is a complex and cumulative effort.[13 14] In this study, we continue the evaluation of the Diabetes Questionnaire by addressing its construct validity. The results in relation to divergent validity show supporting evidence that the Diabetes Questionnaire targets different concepts than the clinical variables for diabetes care traditionally covered by the NDR. Thus, the central aspects covered by the Diabetes Questionnaire including patient perspectives on how they feel, how their diabetes treatment is going, or their experiences of support from diabetes care cannot be measured by HbA_{1c} or other tested clinical variables. Nor can the clinical variables be estimated through the Diabetes Questionnaire. We need the combination. There is a growing emphasis that the perspectives of those living with diabetes should be part of clinical meetings and be given priority among outcomes in diabetes care assessments.[1 5 6 23–25] Supplementing decision-making by adding the patient's perspective is suggested to increase the focus on these aspects in clinical meetings[2 26] and to enhance the quality of care.[26–28] In Sweden, the Patient Act strengthens the patient's position and possibilities for shared decision-making and states that the individual patient's prerequisites and wishes should be taken into account.[29] There is also a growing movement towards person-centred care aiming for partnership that is centred on the patient's experience and individual prerequisites, resources and barriers. An important basis is the patient's story.[30] We hope that the Diabetes Questionnaire can support the patient story if used in the clinical meetings together with the clinical variables.

The Diabetes Questionnaire is unique in being developed to support clinical meetings with individuals and to be used as a means for quality improvement through longitudinal assessment at a local, regional and national levels within the frame of a nationwide healthcare quality register.[7–9] Many other questionnaires for diabetes were developed to target a specific aspect within intervention studies.[3 18 19] The Diabetes Questionnaire has a broad approach with aspects identified as important to adults with diabetes.[8 9] The Diabetes Questionnaire is also developed using the vocabulary and phrasing of people with diabetes,[8] unlike many other questionnaires that often use academic or professional jargon. In this study, we found supporting evidence that the Diabetes Questionnaire is sensitive to statistically significant differences between clinically relevant subgroups with differing levels of glycaemic control. The Diabetes Questionnaire was also in support of convergent validity found to capture some

aspects of generic health-related quality of life, while also in support of divergent validity adding aspects that are not covered by the often-recommended SF-36v2. For routine use within clinical diabetes care, the Diabetes Questionnaire is likely more relevant than the generic SF-36v2. A limitation of the Diabetes Questionnaire is, however, that it is currently only available in Swedish. Consequently, there is limited opportunity for international comparisons. The opportunities and barriers related to clinical use of the Diabetes Questionnaire are currently being studied from the perspectives of professionals and adults with diabetes.

Strengths and weaknesses

Among the strengths of this study are the large and heterogeneous sample of adults with type 1 and type 2 diabetes selected at random from the nation-wide NDR. The respondents were representative of the 2015 population in the NDR (data on file). The results can be considered representative of the Swedish adult population with diabetes related to the coverage rate of about 90% in 2015 when around 40 000 adults with type 1 diabetes and 347 000 with type 2 diabetes were registered in the NDR. Through the NDR, we had access to clinical variables relevant for diabetes care and background data for the non-respondents. Another strength is the use of a well-known measure of health-related quality of life. As there is a lack of agreed-upon benchmarks for how strong positive correlations between questionnaires addressing subjective aspects should be to support convergent construct validity,[31 32] this study based the division of the correlation strength on reports that such correlations generally are low,[31 33] often within the range 0.20–0.40[33] or 0.40–0.60.[31] A correlation of 0.60 has been suggested to be extremely strong, as the random error of measurement of the two questionnaires impede perfect correlations.[31] As the Diabetes Questionnaire and the SF-36v2 do not measure the exact same construct, there were no prerequisites for broad strong correlations.[14 31 33]

Our study also has limitations. The analyses were limited to the respondents and might reflect a group that is more motivated to participate. Another limitation is that the questionnaires were only offered in Swedish, potentially resulting in a higher proportion of foreign-born individuals among the non-responders than among the respondents. Furthermore, the cross-sectional design means that it is not possible to make causal conclusions.

Future perspectives

The evaluation of construct validity is a work of putting the pieces together.[13 14] Consequently, more studies are needed to relate the Diabetes Questionnaire to different concepts and measures. An important task for diabetes care is to identify suitable interventions that adequately can support individuals with diabetes. The Diabetes Questionnaire can be an important contribution to identify the need and focus for targeted interventions, especially for adults with low scores. In future studies, it is important to evaluate the potential of using scores from the Diabetes Questionnaire scales as the primary selection base or in combination with, for example, HbA_{1c} levels or BMI. It is also essential to evaluate whether the Diabetes Questionnaire scales are responsive to actual changes and can be used as an evaluative tool adding patient perspectives to both nursing and medical interventions, longitudinal assessments and quality improvement. The NDR is established as a clinical and a national assessment tool in Swedish diabetes care.[4 34–36] By now, the Diabetes Questionnaire is digitally and freely available for use by all clinics in Sweden connected to the NDR. The Diabetes Questionnaire is also included as the basis for developmental quality indicators in the Swedish national guidelines for diabetes care.[4] In the future, the Diabetes Questionnaire can be among the established quality indicators bringing patient perspectives to the fore for diabetes care.

CONCLUSION

This nation-wide study shows that the Diabetes Questionnaire captures some generic health-related quality of life dimensions as well as adds diabetes-specific information not covered by the SF-36v2 and clinical variables. The Diabetes Questionnaire is also sensitive to differences between clinically relevant groups of glycaemic control.

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Contributors MSE made substantial contributions to the design of the work, applying for ethical approval and funding, interpreting the data and drafting and revising the manuscript (major contributor). JL and U-BJ supervised and made substantial contributions to the design of the work, applied for funding, made intellectual contributions in the interpretation of the data, critically revised the manuscript for important intellectual content, and contributed experience and knowledge from diabetes care and research in diabetes and health-related quality of life. SB made substantial contributions to the design of the work, made intellectual contributions in the interpretation of the data and critically revised the manuscript for important intellectual content. BP made substantial contributions to the design of the work; performed the selection of the random sample; made intellectual contributions in the interpretation of the data; critically revised the manuscript for important intellectual content, and contributed statistical advice, experience and knowledge in the research of generic health-related quality of life

and patient-reported outcome. SF made substantial contributions to the design of the work, contributed substantial statistical advice, was the major contributor in analysing the data, made substantial intellectual contributions in the interpretation of the data, and critically revised the manuscript for important intellectual content. SG supervised and made substantial contributions to the design of the work; applied for ethical approval and funding; made intellectual contributions in interpretation of the data; critically revised the manuscript for important intellectual content, and contributed medical experience and knowledge from diabetes care, diabetes research, and research using healthcare quality registers. KE-O supervised and made substantial contributions to the design of the work; applied for ethical approval and funding; generated the SF-36v2 data; interpreted the data; critically revised the manuscript for important intellectual content, and contributed medical experience and knowledge from diabetes care, diabetes research and research using healthcare quality registers. All authors read and approved the final manuscript as well as consented to be on the author list.

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Patient consent for publication Not required.

Ethics approval The study conforms to the Declaration of Helsinki and was approved by the Regional Ethical Review Board in Gothenburg, Sweden (No. 029-15, T600-15). Participants gave their informed consent. The letter to the participants contained information about the study's purpose, the voluntary nature of their participation and their right to end participation. The letter also disclosed information about the NDR, methods of handling personal data, confidentiality measures and contact details.

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