



Validated functional scales among adults with and without type 2 diabetes mellitus: study to help improve early evaluation and management of risk factors leading to diabetes (SHIELD)

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Abstract

Background: To evaluate whether diminished functionality among adults with type 2 diabetes mellitus (T2DM) is due to implications associated with diagnosis of T2DM, or due to underlying characteristics that predispose to T2DM and ill health.

Methods: This prospective SHIELD study classified respondents into 3 groups: (1) T2DM diagnosis at baseline in 2004, (2) newly diagnosed T2DM from 2005–2009 (ie, “at risk” for T2DM at baseline), and (3) no DM diagnosis at baseline or from 2004–2009. Validated assessments included SF-12 (quality of life), PHQ-9 (depression), IPAQ (physical activity), and WPAI-GH (work impairment). Regression models adjusted for age, obesity, cigarette smoking, cholesterol problems, heart disease, and hypertension.

Results: SF-12 physical health scores were similar between those with T2DM (40.7, n=1837) and at risk for T2DM (41.6, n=473) ($p>0.05$), but worse versus those without DM (46.5, n=4629) ($p<0.01$). Depression scores, work impairment, and physical activity were similar between those with T2DM and at risk for T2DM ($p>0.05$), but worse than for those without DM ($p<0.01$). Age, obesity, cholesterol problems, and cigarette smoking consistently predicted functioning scores after adjusting for diabetes status.

Conclusions: Age, cigarette smoking, and obesity were factors that had stronger influences on functional scale scores than the diagnosis of T2DM.

Keywords: Type 2 diabetes, health-related quality of life, depression, physical activity, work and activity impairment

Introduction

Adults with type 2 diabetes mellitus (T2DM) are known to have lower health-related quality of life (HRQOL) and more depressive symptomatology than adults without T2DM [1–4]. Patients with T2DM also have diminished health status relative to patients with other chronic diseases [1]. Obesity and a diagnosis of T2DM may be independent predictors of overall work impairment and life disruption, with the Work Productivity and Activity Impairment (WPAI) Questionnaire suggesting that among individuals with T2DM, those who were obese had the greatest impairment at work, greatest impairment of daily activities, and greatest overall impairment [5].

It is unclear whether the lower physical and mental health functioning among the general population of adults with T2DM is related to the psychological implications and comorbidities associated with T2DM, or whether the diminished functional status is due to underlying health factors and behaviors that lead to T2DM itself. It is true that many select patients with diabetes have complications that adversely affect health.

Diabetes complications, including blindness, kidney disease, cardiovascular disease, and neuropathy, have a negative

impact on HRQOL. Among patients with T2DM, the number of diabetes complications is correlated with lower HRQOL scores [4]. A mailed questionnaire to individuals with T2DM in Norway ascertained that EQ-5D health status scores were lower for those with diabetes complications than for those without complications [6].

So clearly for the individual patient with T2DM, diabetes mellitus complications can be a determining factor with regard to functionality and quality of life. However, among a general T2DM population not specifically selected for complications, other factors may be present that might also explain why adults with T2DM have lower functioning (physical and mental) than adults without T2DM. Approximately 40%–50% of patients with diabetes are obese [7]. Epidemiological studies have found that age, family history of diabetes, obesity, low physical activity, and hypertension are risk factors for T2DM [8,9].

The Study to Help Improve Early evaluation and management of risk factors Leading to Diabetes (SHIELD), a large, longitudinal, population-based survey, followed adults without T2DM for 5 years and found that increasing age, family history of T2DM, high body mass index (BMI), abdominal obesity, excessive thirst,

asthma, and gestational diabetes significantly increased the risk of developing T2DM [10]. In a subsequent analysis of the SHIELD data, a simplified set of self-reported predictors for T2DM found that among those aged ≥ 55 years with BMI ≥ 30 kg/m² and family history of diabetes, 20% of individuals reported developing T2DM in 5 years, compared with 0.3% of individuals who had none of these predictors [11]. Taken together, older age, obesity, cigarette smoking, and dyslipidemia may also contribute to ill health and lower physical functioning and poor mental health.

Thus, it may not be intuitively obvious why patients with T2DM have reduced functional scores. Is it the diagnosis of T2DM or other underlying characteristics that impact functioning? The objective of the present survey study was to compare scores of validated functional scales among adults with T2DM, among those at risk for developing T2DM, and among those who did not report developing T2DM during a 5-year period.

Methods

This analysis reflects data derived from SHIELD assessing the association between physical and mental health functioning, diabetes status, and patient characteristics. SHIELD was a 5-year, survey-based study conducted to better understand patterns of health status, health behavior, and quality of life of people living with diabetes and those with varying levels of cardiometabolic risk. The SHIELD study was approved by the Quorum Review Board.

SHIELD Survey

SHIELD included an initial screening phase to identify cases of interest in the general adult population (eg, patients with type 2 or type 1 diabetes, individuals at risk for developing T2DM), a baseline survey to follow up identified cases with a questionnaire about health status, health knowledge and attitudes, and current behaviors and treatments, and annual follow-up surveys. A detailed description of the SHIELD methodology has been published previously [12,13].

In brief, the screening survey was mailed in April 2004 to a stratified random sample of 200,000 US households, representative of the US population for geographic residence, household size and income, and age of head of household [14], identified by the Taylor Nelson Sofres National Family Opinion (TNS NFO) panel (Greenwich, CT). All TNS NFO surveys were voluntary, and no special incentives were provided. A response rate of 64% (128,000 households with data on 211,097 individuals) was obtained for the screening survey.

A comprehensive baseline survey was mailed in September-October 2004 to a representative sample of adults ($n = 22,001$) who were identified in the screening survey as having self-reported type 1 or T2DM, no diabetes, or being at risk for T2DM. Each respondent group was balanced to be representative of that segment of the population for age, gender, geographic region, household size, and income for the US population,

and then a random sample from each group was selected and sent the baseline survey. A response rate of 72% was obtained for the baseline survey. Response rates to the 2005–2009 annual follow-up surveys were 69%–75%. Respondents to the baseline survey and the 2009 survey were included in the analysis.

Study measures

Respondents were classified as having T2DM based on their self-report of having been told by a doctor, nurse, or other healthcare professional that they had T2DM. Although it is true that an increasing number of patients with T2DM have been diagnosed at younger ages, for the purposes of improving selectivity with this survey study, the diagnosis of T2DM required an age of diagnosis of 21 years or older.

Respondents meeting the *a priori* criteria for a diagnosis of T2DM at the baseline survey in 2004 were categorized as having T2DM at baseline. Respondents who did not report a diagnosis of type 1, type 2, or unspecified diabetes at the baseline survey but reported a diagnosis of T2DM at any of the annual surveys between 2005 and 2009 were categorized as having newly diagnosed T2DM (ie, “at risk” for T2DM at baseline). For the purpose of this paper, the term of “at risk for T2DM” is not meant to be all inclusive of patients at risk of T2DM since many patients are unaware of their risk and diagnosis is delayed; rather the term was meant to reflect those respondents with no T2DM at baseline who subsequently reported a new diagnosis of T2DM during 2005–2009. Respondents who reported no type 1, type 2, or unspecified diabetes diagnosis at baseline or from 2005 to 2009 in the annual surveys were categorized as having no diabetes. These three groups (T2DM at baseline, “at risk” for T2DM, and no diabetes) were assessed for physical and mental functioning through the use of validated functional scales.

Physical and mental HRQOL was evaluated using the Medical Outcomes Study Short Form-12 (SF-12) version 2 questionnaire. The SF-12 is a brief and reliable generic measure of overall health status [15]. The SF-12 measures 8 domains of health: physical functioning, role limitations because of physical health, bodily pain, general health perceptions, vitality, social functioning, role limitations because of emotional problems, and mental health. The recall period was the past 4 weeks. SF-12 responses were scored from 0 to 100 on the physical component summary (PCS) scale and mental component summary (MCS) scale. Higher scores indicate better HRQOL. To simplify comparisons with the general population, norm-based scoring was used. In norm-based scoring, scores are linearly transformed to a scale with a mean of 50 and standard deviation (SD) of 10 for the general population [15].

Depression was assessed using the Patient Health Questionnaire (PHQ-9). The PHQ-9 focuses on the 9 signs and symptoms of depression from the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV) [16]. The PHQ-9 is used to establish a depressive disorder diagnosis

as well as provide a symptom severity score. Higher scores indicate increasing severity of depression. A PHQ-9 score of 5–9 indicates minimal depressive symptoms, a score of 10–14 is minor depression or mild major depression, a score of 15–19 is moderately severe major depression, and a score >20 indicates severe major depression [16].

The type and length of physical activity over the previous 7 days were assessed through the 7-item International Physical Activity Questionnaire (IPAQ) short form [17]. The IPAQ scores are categorized into 3 levels: (1) low or inactive, (2) moderate activity of 3 or more days of vigorous activity of at least 20 minutes per day or 5 or more days of moderate activity or walking of at least 30 minutes per day, and (3) high activity of vigorous activity on at least 3 days or 7 days of any combination of walking and moderate or vigorous activities.

Work and daily activity performance were evaluated with the Work Productivity and Activity Impairment Questionnaire: General Health (WPAI-GH), version 2 [18]. The WPAI-GH is a 6-item questionnaire that assesses work productivity by measuring absenteeism (work time missed), presenteeism (impairment at work/reduced on-the-job effectiveness), work productivity loss (overall work impairment that adds absenteeism and presenteeism), and impairment of daily activities (ie, work around the house, shopping, exercising, childcare, studying). Absenteeism was measured as the number of hours missed from work in the past 7 days because of health problems, adjusting for hours actually worked and hours missed because of vacation or holidays.

Presenteeism and activity impairment for the past 7 days were assessed using a Likert scale of 0 to 10, with anchors at 0 (health problems had no effect on my work/daily activities) and at 10 (health problems completely prevented me from working/doing my daily activities). The response to the Likert scale was multiplied by 100 to express the degree of affected productivity in percentages and then divided by 10 to indicate the percentage impairment. Higher scores indicated greater impairment. The WPAI has good validity and reliability [18] and has proved to be a useful tool to measure the relative difference between groups in clinical trials [19,20] and in subjects with and without disease [21,22].

Weight and height were self-reported at the time of the surveys. Overweight was defined as BMI of 25.0–29.9 kg/m², and obese was defined as BMI ≥30 kg/m². Comorbid conditions were self-reported based on survey questions of being told by a healthcare professional that they had the condition. Cigarette smoking status was quantified as never smoked, quit smoking, or currently smoking.

Statistical analysis

Mean (SD) scores for the SF-12, PHQ-9, and WPAI overall work impairment and activity impairment were computed for each of the three disease groups from the 2004 baseline and 2009 follow-up surveys. The number and percentage of respondents in each IPAQ activity level and PHQ-9 depression level were

computed for each disease group from the 2004 baseline and 2009 follow-up surveys. Comparisons across disease groups were made using chi-square tests for categorical variables and ANOVA for continuous variables. Additionally, pairwise *t*-tests were used to compare scores between each disease group. Linear regression with partial correlation coefficients was used to identify predictors of the SF-12, PHQ-9, and WPAI scores, adjusting for age, cholesterol problems, heart disease/heart attack, hypertension, obesity, and current cigarette smoking. Logistic regression was used to identify predictors of the IPAQ activity levels, adjusting for the same factors. Statistical significance was set *a priori* as *p*<0.05.

A total of 6939 (54.2%) respondents completed the 2004 and 2009 SHIELD surveys, did not have type 1 diabetes, and were included in the analysis (Figure 1). Approximately 5866 (45.8%) respondents who completed the 2004 baseline survey did not complete the 2009 survey. Respondents included in the analysis were statistically significantly different from respondents who were excluded because they were lost to follow-up; however, the differences were not large (data not shown). Eligible respondents were approximately 3 years older than the excluded respondents, and 62% of the eligible respondents were women versus 59% of the excluded respondents. There were fewer T2DM at baseline respondents (26.5%) among the eligible respondents compared with the excluded respondents (35.1% T2DM at baseline).

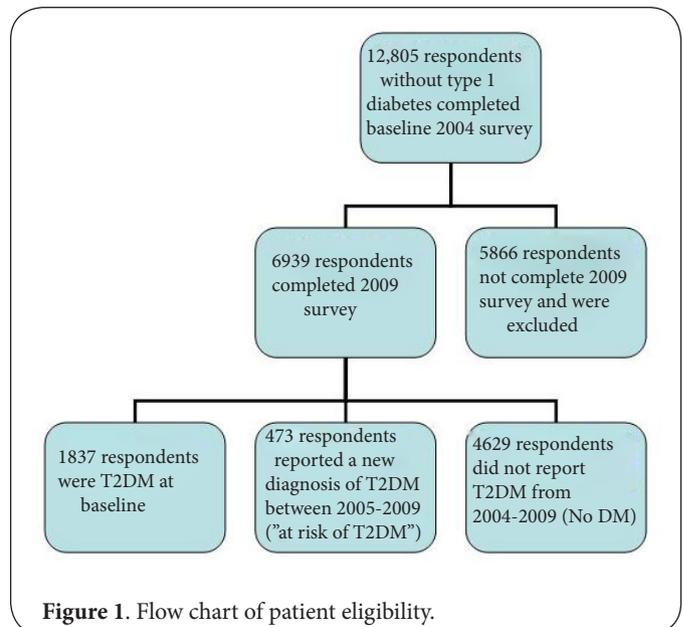


Figure 1. Flow chart of patient eligibility.

Results

Among the eligible respondents (*n* = 6939), 1837 (26%) reported T2DM at baseline, 473 (7%) were designated as “at risk” for T2DM (reported newly diagnosed T2DM between 2005 and 2009), and 4629 (67%) reported no diabetes at baseline and through 2009. The three groups differed at baseline in

age, racial composition, education, household income, BMI, and prevalence of specific comorbid conditions ($p < 0.0001$) (Table 1). These differences were largely with the no-diabetes group compared with the T2DM-at-baseline and the “at-risk”-for-T2DM groups. The T2DM-at-baseline group was similar to the “at-risk”-for-T2DM group ($p > 0.05$) with regard to age, gender, race, education, income, and prevalence of heart disease/heart attack. However, the “at-risk”-for-T2DM group was heavier and had more obese respondents (73.7%) compared with the T2DM-at-baseline group (62.4%, $p < 0.0001$). Fewer “at-risk”-for-T2DM respondents reported cholesterol problems than T2DM-at-baseline respondents ($p = 0.004$). Respondents with no diabetes were younger, more educated, and had higher household incomes and, lower BMI, and fewer had cholesterol problems, heart disease, and hypertension than respondents with either T2DM at baseline or “at risk” for T2DM.

Physical and mental health functioning

Baseline scores on the IPAQ, SF-12 physical health, PHQ-9, and WPAI were significantly different across the 3 diabetes groups (Table 2). Baseline SF-12 mental health scores did not differ across the groups. Comparing T2DM-at-baseline respondents with “at-risk”-for-T2DM respondents, baseline scores on the functioning scales were similar; 11.5% of T2DM-at-baseline respondents and 12.1% of “at-risk”-for-T2DM respondents were highly active based on IPAQ scores. Additionally, 16.9% of T2DM-at-baseline respondents and 16.6% of “at-risk”-for-T2DM respondents had moderate to severe depression at baseline based on PHQ-9 scores. However, the no-diabetes group differed from the T2DM-at-baseline group for most of the functioning scales at baseline. The T2DM-at-baseline group had significantly fewer respondents highly active, had lower SF-12 HRQOL scores, more depression, and greater work and activity impairment than the no-diabetes group ($p < 0.01$ for each scale).

A similar pattern of no differences between the T2DM-at-baseline group and “at-risk”-for-T2DM group but worse scores than the no-diabetes group was evident in the 2009 scores on the IPAQ, SF-12, PHQ-9, and WPAI (Table 3). At 5-year follow-up, scores on the functioning scales were similar between the T2DM-at-baseline group and “at-risk”-for-T2DM group. However, there were fewer highly active and more depressed respondents in the T2DM-at-baseline group than in the no-diabetes group ($p < 0.01$ for IPAQ and PHQ-9). SF-12 physical health scores were significantly lower (worse HRQOL) and WPAI scores significantly higher (more work and/or activity impairment) for T2DM-at-baseline group than in the no-diabetes group ($p < 0.01$ for SF-12 PCS and WPAI).

In the regression analysis, T2DM-at-baseline and “at-risk”-for-T2DM groups had significantly different ($p < 0.05$) adjusted mean SF-12 PCS scores and PHQ-9 scores than the no-diabetes group, after adjusting for age, cholesterol problems, heart disease, hypertension, obesity, and cigarette smoking (Table 4). For SF-12 MCS and IPAQ, the T2DM-at-baseline-group had

Table 1. Characteristics of respondents with and without type 2 diabetes mellitus at baseline.

Characteristics	T2DM at baseline N =1837	At risk for T2DM N =473	No DM N =4629
Age, years, mean (SD)*	60.6 (11.8)	58.7 (12.0)	56.3 (15.0)
Women, %	60.4	64.5	62.6
Race, %*			
White	87.7	91.0	92.0
Black	10.1	6.8	6.0
Other (Asian, American Indian, other)	2.1	2.2	2.0
Spanish origin, %	2.6	1.3	1.9
Education, %*			
High school diploma or less	34.9	33.6	28.4
Some college or college degree	52.1	53.3	55.5
Postgraduate degree	13.0	13.1	16.1
Annual income, %*			
<\$22,500	29.9	24.7	22.3
\$22,500–\$39,999	22.3	26.2	19.5
\$40,000–\$59,999	17.3	16.3	18.6
>\$59,999	30.5	32.8	39.6
Body mass index*, kg/m ²			
Mean (SD)*	33.7 (8.0)	34.5 (7.2)	29.8 (6.8)
Normal weight, %	9.6	7.1	24.0
Overweight, %	28.0	19.3	32.7
Obese, %	62.4	73.7	43.3
Comorbid conditions, %			
Cholesterol problems*	73.6	66.8	53.7
Heart disease/heart attack*	19.2	18.4	13.0
High blood pressure/hypertension*	68.4	63.4	46.7
Cigarette smoking status, %			
Current smoker	14.7	16.6	14.6
Past or never smoked	85.3	83.4	85.4

* $p < 0.0001$ across all 3 groups
 DM: diabetes mellitus; SD: standard deviation; T2DM: type 2 diabetes mellitus

significantly different ($p < 0.05$) adjusted mean scores than the no-diabetes group, but the “at-risk”-for-T2DM group was not significantly different ($p > 0.10$) from the no-diabetes group. For

Table 2. Baseline scores for scales of physical and mental health functioning by disease status.

	T2DM at baseline N = 1837	At risk for T2DM N = 473	No DM N = 4629
IPAQ score (physical activity)*	N = 1786	N = 454	N = 4482†
Inactive, %	78.4	78.6	70.1
Moderately active, %	10.1	9.3	13.9
Highly active, %	11.5	12.1	16.0
SF-12 PCS – physical health, mean (SD)*	40.72 (12.69) N = 1668	41.55 (12.20) N = 418	46.50 (11.59)† N = 4251
SF-12 MCS - mental health, mean (SD)	50.26 (10.32) N = 1668	49.94 (11.09) N = 418	50.46 (10.12) N = 4251
PHQ-9– depression*			†
Mean (SD)*	4.86 (5.32) N = 1738	4.99 (5.39) N = 452	4.03 (4.83)† N = 4438
No to minimal depression, %	61.9	59.5	68.6
Mild depression, %	21.2	23.9	19.5
Moderate depression, %	10.2	10.2	6.8
Severe depression, %	6.7	6.4	5.0
Work Productivity and Activity Impairment (WPAI)			
Work impairment for those who work, mean (SD)*	11.93 (19.36) N = 669	12.75 (18.95) N = 178	9.46 (17.40)† N = 2302
Activity impairment for all respondents, mean (SD)*	27.01 (29.04) N = 1815	27.11 (29.16) N = 464	19.48 (26.26)† N = 4548

*p<0.01 for comparison across all 3 groups; †p<0.01 for comparison of T2DM-at-baseline group with No-DM group
 DM: diabetes mellitus; IPAQ: International Physical Activity Questionnaire; MCS: mental component summary; PCS: physical component summary; PHQ: Patient Health Questionnaire; SF: Short Form; T2DM: type 2 diabetes mellitus

work impairment, mean scores did not differ (p>0.05) across the diabetes groups after adjusting for age, cholesterol problems, heart disease, hypertension, obesity, and cigarette smoking. Age, cholesterol problems, obesity, and cigarette smoking were consistently predictive of the functioning scale scores

Table 3. Five-year follow-up scores for scales of physical and mental health functioning by disease status.

	T2DM at baseline N = 1837	At risk for T2DM N = 473	No DM N = 4629
IPAQ score (physical activity)*			†
Inactive, %	67.4	64.1	57.7
Moderately active, %	20.6	23.7	25.7
Highly active, %	11.9	12.2	16.7
SF-12 PCS–physical health, mean (SD)*	39.5 (12.8)	40.2 (12.5)	45.5 (11.9)†
SF-12 MCS-mental health, mean (SD)	52.2 (10.6)	51.8 (11.0)	52.5 (9.8)
PHQ-9– depression*			†
Mean (SD)*	4.2 (5.1)	4.4 (5.5)	3.4 (4.6)†
No to minimal depression, %	66.5	66.4	74.1
Mild depression, %	19.8	18.9	16.6
Moderate depression, %	7.5	7.8	5.3
Severe depression, %	6.2	6.9	3.9
Work Productivity and Activity Impairment (WPAI)			
Work impairment for those who work, mean (SD)*	11.3 (19.3)	12.6 (21.2)	8.8 (17.4)†
Activity impairment for all respondents, mean (SD)*	32.3 (31.8)	31.3 (32.6)	22.0 (28.3)†

*p<0.01 for comparison across all 3 groups; †p<0.01 for comparison of T2DM-at-baseline group with No-DM group
 DM: diabetes mellitus; IPAQ: International Physical Activity Questionnaire; MCS: mental component summary; PCS: physical component summary; PHQ: Patient Health Questionnaire; SF: Short Form; T2DM: type 2 diabetes mellitus

(p<0.05 for each scale), even after adjusting for diabetes status and the other factors in the model. Heart disease was also predictive of the functioning scores for the SF-12 PCS and MCS, PHQ-9, and IPAQ but not for the WPAI. Hypertension was predictive of the SF-12 PCS, PHQ-9, and IPAQ scores but not for the WPAI. Partial correlation coefficients were largest for age and obesity in the SF-12 PCS model, PHQ-9 model, and WPAI model. Partial correlation coefficients were largest for age and cigarette smoking in the SF-12 MCS model, and odds ratios were largest for obesity and cigarette smoking

Table 4. Regression coefficients and partial correlation coefficients for scales of physical and mental health functioning, adjusting for age, cholesterol problems, heart disease/heart attack, hypertension, obesity, and cigarette smoking.

Characteristics	Beta coefficient (95% CI)	Odds Ratio	P-value
SF-12 PCS			
T2DM at baseline vs. No DM	-3.21 (-3.91, -2.51)	-0.11	<0.0001
At risk for T2DM vs. No DM	-2.35 (-3.52, -1.18)	-0.05	<0.0001
Age	-0.17 (-0.20, -0.15)	-0.17	<0.0001
Cholesterol problems	-0.96 (-1.62, -0.29)	-0.03	0.005
Heart disease/heart attack	-4.30 (-5.16, -3.44)	-0.12	<0.0001
High blood pressure/hypertension	-3.13 (-3.80, -2.46)	-0.11	<0.0001
Obese	-5.57 (-6.19, -4.95)	-0.21	<0.0001
Current smoker	-3.60 (-4.44, -2.77)	-0.10	<0.0001
SF-12 MCS			
T2DM at baseline vs. No DM	-0.72 (-1.33, -0.10)	-0.03	0.022
At risk for T2DM vs. No DM	-0.78 (-1.80, 0.24)	-0.02	0.14
Age	0.17 (0.15, 0.19)	0.21	<0.0001
Cholesterol problems	-0.64 (-1.23, -0.06)	-0.03	0.030
Heart disease/heart attack	-1.42 (-2.18, -0.66)	-0.05	<0.0001
High blood pressure/hypertension	-0.45 (-1.03, 0.14)	-0.02	0.13
Obese	-0.76 (-1.30, -0.22)	-0.04	0.006
Current smoker	-1.93 (-2.67, -1.20)	-0.07	<0.0001
PHQ-9			
T2DM at baseline vs. No DM	0.58 (0.30, 0.87)	0.05	<0.0001
At risk for T2DM vs. No DM	0.53 (0.05, 1.02)	0.03	0.031
Age	-0.05 (-0.06, -0.04)	-0.13	<0.0001
Cholesterol problems	0.45 (0.18, 0.72)	0.04	0.001
Heart disease/heart attack	0.84 (0.49, 1.20)	0.06	<0.0001
High blood pressure/hypertension	0.49 (0.21, 0.76)	0.04	<0.0001
Obese	1.22 (0.97, 1.48)	0.12	<0.0001
Current cigarette smoker	0.86 (0.52, 1.20)	0.06	<0.0001
WPAI, Overall Work Impairment			
T2DM at baseline vs. No DM	1.08 (-0.94, 3.10)	0.02	0.30
At risk for T2DM vs. No DM	3.17 (-0.22, 6.56)	0.04	0.07
Age	-0.11 (-0.19, -0.04)	-0.07	0.002
Cholesterol problems	2.48 (0.84, 4.13)	0.06	0.003
Heart disease/heart attack	0.46 (-2.65-3.57)	0.01	0.77
High blood pressure/hypertension	1.43 (-0.31, 3.18)	0.03	0.11
Obese	3.83 (2.23, 5.42)	0.10	<0.0001
Current smoker	2.84 (0.73, 4.95)	0.06	0.008
IPAQ		Odds Ratio*	
T2DM at baseline vs. No DM	-0.18	0.83 (0.74, 0.95)	0.005
At risk for T2DM vs. No DM	0.03	1.03 (0.83, 1.27)	0.80

Continuation of Table 4.

Characteristics	Beta coefficient (95% CI)	Odds Ratio	P-value
Age	-0.01	NA	<0.0001
Cholesterol problems	0.18	1.20 (1.07, 1.34)	0.002
Heart disease/heart attack	0.19	1.20 (1.03, 1.41)	0.022
High blood pressure/hypertension	0.24	1.27 (1.13, 1.43)	<0.0001
Obese	0.60	1.82 (1.63, 2.03)	<0.0001
Current cigarette smoker	0.28	1.33 (1.14, 1.54)	<0.0001

*odds of being highly active vs. not highly active

DM: diabetes mellitus; IPAQ: International Physical Activity Questionnaire; MCS: mental component summary; PCS: physical component summary; PHQ: Patient Health Questionnaire; SF: Short Form; T2DM: type 2 diabetes mellitus; WPAI: Work Productivity and Activity Impairment

in the IPAQ model.

Discussion

In this population-based study, functional scale scores were similar between T2DM-at-baseline respondents and “at-risk”-for-T2DM respondents, with both groups having significantly worse scores, compared with respondents with no diabetes. Thus, the novel finding of this study was that age, obesity, and cigarette smoking were factors that appeared to have stronger influences on the functional scale scores than the diagnosis of T2DM itself. Additionally, cardiovascular conditions also had a significant impact on scale scores for physical health HRQOL, depression, and physical activity after adjusting for diabetes status.

The clinical implication of this finding is that not only are age, cigarette smoking, and obesity important risk factors for T2DM and/or its complications, but that these risk factors also largely contribute to diminished functional status, as objectively assessed by scales for physical health, depression, work impairment, and physical activity. In fact, the risk factors of age, cigarette smoking, and obesity may be more correlated to diminished functionality than the diagnosis of T2DM itself.

The clinical implications for the patient are that avoiding the diagnosis of T2DM (through neglecting appropriate screening) may not be the best strategy to avoid diminished mental and physical functionality. Rather, this study suggests that modifiable risk factors such as cigarette smoking and excessive body fat are not only major contributors to T2DM itself, but also the major contributors to future diminished physical and mental health functioning. Hence, pro-active measures to diagnose T2DM and its cause, with a specific emphasis on health factors such as cigarette smoking and obesity may not only be expected to improve objective glucose and other more objective metrics, but such measures might also be expected to improve the lives of patients with T2DM. This would be supported by the use of the validated instruments utilized in this study, which included IPAQ (physical activity), Medical Outcomes Study Short Form-12 (SF-12) (physical and mental HRQOL), PHQ-9 (depression), and WPAI (Work

Productivity and Activity Impairment).

The present study findings are similar to previous studies of the diminished health status among adults with type 2 diabetes. Reduced HRQOL and more depression among individuals with type 2 diabetes than adults without diabetes were observed in this study as well as other studies [1-4]. The present study also confirmed greater work impairment and activity impairment among adults with type 2 diabetes that was found in an earlier investigation of the SHIELD data [5].

A limitation of this analysis is that the determination of T2DM, other comorbid conditions, and weight was made based on self-report rather than on clinical or laboratory measures. However, this determination was made consistently for all respondent groups evaluated in this study, so it should not have affected the comparison across groups. Nonetheless, it is possible that some of the similarities between T2DM-at-baseline and “at-risk”-for-T2DM respondents could be partly explained due to “at-risk” respondents actually having T2DM, if otherwise assessed objectively via blood testing instead of self report. Comorbid conditions such as neuropathy and nephropathy were not included in the analysis since data for these comorbid conditions was not collected in SHIELD. Adults with T2DM and those that developed diabetes over the 5 years (at-risk for T2DM) may have had better recall of comorbid conditions than adults without diabetes due to more interactions with healthcare professionals to manage their disease. However, numerous studies have shown that many patients with T2DM also have dyslipidemia, hypertension, and heart disease. Additionally, household panels, like the SHIELD study, tend to underrepresent the very wealthy and very poor segments of the population and do not include military or institutionalized individuals. These limitations are true for most random sampling and clinically based methodologies. Self-selection bias may be present because respondents were those who could read and comprehend the survey. Another limitation is that the T2DM individuals surveyed included a general population of T2DM, and did not specifically select T2DM patients with clinically significant T2DM complications. Thus, this analysis should not be interpreted as

comparing the functional scores of individual T2DM patients with severe diabetes complications (eg, retinopathy, nephropathy, neuropathy, dermopathy) versus those without these debilitating diabetes complications. Small differences in patient characteristics between respondents included in the analysis and those excluded (lost to follow-up) may have introduced selection bias. Thus, the study findings may not be generalizable to all adults with or at-risk for T2DM since some individuals were lost to follow-up over 5 years of study. Finally, although survey studies are limited because they rely on subjective reports, it is the nature of many scales that they represent subjective reporting. It is for that reason that the outcomes of this analysis are the subjective answers to validated functional scales.

In conclusion, although individuals with severe complications of T2DM may have physical and mental functioning differences, this self-reported survey among a general population of T2DM individuals suggests that functioning scale scores of individuals with T2DM may be similar to those at risk for T2DM, with both having significantly worse scores compared with individual without diabetes, an effect correlated with age, obesity, cholesterol problems, and cigarette smoking.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

Authors' contributions	HEB	KMF	SG
Research concept and design	✓	✓	✓
Collection and/or assembly of data	--	--	✓
Data analysis and interpretation	✓	✓	✓
Writing the article	--	✓	--
Critical revision of the article	✓	--	✓
Final approval of article	✓	✓	✓
Statistical analysis	--	✓	--

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