Change in Health Status (EQ-5D) Over 5 Years Among Individuals With and Without Diabetes

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BACKGROUND

- Studies have demonstrated that adults with type 2 diabetes mellitus have a lower health-related quality of life (below population norms) than adults without diabetes[1]
- Lower health status as rated by the EQ-5D has been documented in individuals with T2DM[2]
- EQ-5D utility scores are instrumental in economic evaluations to estimate the QALYs gained for disease states and therapeutic interventions
- However, many of the HRQOL studies among adults with T2DM using the EQ-5D have been short term and have not assessed change over years

OBJECTIVES

- To assess the change in health status and HRQOL over 5 years among individuals with and without T2DM

METHODS

Study Design

- Longitudinal analysis of EQ-5D data collected in 2004 and 2009 among SHIELD respondents with T2DM and no diabetes
- **S**tudy to **H**elp **I**mprove **E**arly evaluation and management of risk factors **L**eading to **D**iabetes (SHIELD) is a 5-year population-based survey conducted to better understand the risk for the development of diabetes, as well as disease burden
  - Based upon a screening questionnaire mailed to 200,000 nationally representative households (TNS NFO Household Panel), responses for 211,097 adults from 127,420 households were obtained (64% response rate)
  - A baseline survey was sent in 2004 to 22,001 selected individuals derived from the screening respondents. Since 2005, annual SHIELD surveys have captured self-reported information on health status, attitudes and behaviors, quality of life, and anthropometry from this representative sample of the US population
  - The 2009 survey collected information from 14,921 individuals (71% response rate), and 2,671 respondents had T2DM (18%)

Study Population

- Respondents were 18 years of age or older
- Self-reported diagnosis of T2DM was based on being "told by a doctor, nurse or other healthcare professional that you have type 2 diabetes"
- Respondents who did not report a diagnosis of T2DM, T1DM, or unspecified DM were included in the "no diabetes" group

Study Measures

- EQ-5D was administered in the SHIELD survey at baseline (2004) and 5 years later (2009)
  - EQ-5D includes a descriptive health profile and a single index value for health status[3,4]
  - Visual Analog Scale records the respondent's self-rated current health status on a graduated scale of 0–100, with higher scores representing higher/ better HRQOL
  - EQ-5D descriptive system includes 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, which is converted into an index score (utility value) using US population weights[5]
- Respondents were classified as having retinopathy if they reported a diagnosis of eye disease, blindness or retinopathy. Neuropathy was defined as reporting a diagnosis of nerve problems of hands or feet involving pain, tingling, or numbness, foot ulcers, or amputation. Nephropathy was defined as a diagnosis of chronic kidney disease, dialysis, end-stage kidney disease, kidney transplant, or protein in the urine

METHODS (Continued)

Statistical Analyses

- VAS score and health index score were computed at baseline and 5 years later, and the change over 5 years measured for respondents with and without T2DM
- Comparisons between respondents with and without reported T2DM were conducted using chi-square test for categorical variables and *t*-tests for continuous variables
- Linear regression model was used to determine change in EQ-5D score, controlling for age, gender, education, household income, body mass index, and diabetes status (T2DM vs. no diabetes)
- Statistical significance was set *a priori* as $p < 0.05$. Minimally important difference for the EQ-5D index score is 0.06 and 0.07 for the EQ-5D VAS score[6-7]

RESULTS

- There were 1,741 respondents with T2DM and 4,543 respondents without diabetes who completed the 2004 and 2009 EQ-5D questionnaires and were included in the analysis

Table 1. Characteristics of SHIELD respondents with and without T2DM who completed the 2004 and 2009 EQ-5D questionnaires, n = 6,284

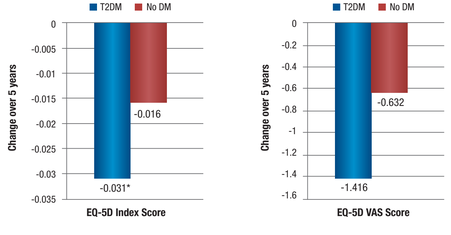
Characteristics	T2DM (n=1,741)	No Diabetes (n=4,543)
Age, years, mean (SD)	60.6 (11.7)*	56.1 (15.0)
Women, %	60.2	62.4
White, %	85.4*	89.5
Education, high school degree or less, %	35.1*	28.5
Household income <$40,000, %	51.9*	41.8
BMI, kg/m^2, mean (SD)	33.7 (8.0)*	29.8 (6.9)
Diabetes duration, years, mean (SD)	9.0 (7.8)	Not applicable

*p<0.001

- T2DM respondents were significantly older, had higher BMI, and a greater percentage with low education and low household income, compared with respondents without diabetes (Table 1)

Change in EQ-5D Over 5 Years

Figure 1. Absolute change in EQ-5D score from 2004 to 2009 among adults with and without T2DM



*p = 0.001 for comparison between T2DM and No DM

- There was a significantly greater decline in EQ-5D index score in the T2DM group compared with those without diabetes over the 5-year period (p = 0.001) (Figure 1)
- EQ-5D VAS score declined over 5 years for both groups, but the difference between T2DM and No DM was not statistically significant (p = 0.09)

RESULTS (Continued)

Table 2. Multivariate linear regression for change in EQ-5D index score among adults with and without T2DM

Variables	Beta coefficient (SE)	p-value
T2DM vs. No DM	-0.015 (0.004)	0.001
Age, years (continuous, per 1 year)	-0.001 (0.000)	<0.0001
Women vs. men	0.008 (0.004)	0.04
Black vs. white	0.004 (0.007)	0.57
Other race vs. white	0.018 (0.013)	0.16
BMI, kg/m^2	0.000 (0.000)	0.08
Income (referent: <$22,500)		
$22,500 – $39,999	-0.001 (0.006)	0.82
$40,000 – $59,999	-0.006 (0.006)	0.30
$60,000 – $89,999	0.002 (0.006)	0.70
>$89,999	0.005 (0.006)	0.40
Education (referent: high school degree)		
Some high school	0.004 (0.010)	0.72
Some college	0.000 (0.005)	0.93
College graduate	0.002 (0.006)	0.71
Graduate courses/degree	-0.001 (0.006)	0.88

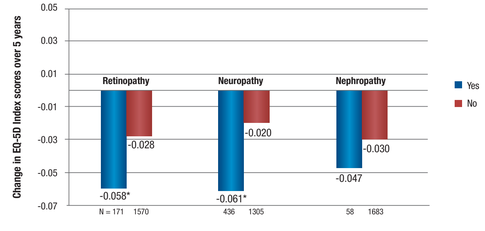
- Compared with respondents without diabetes, those with T2DM had a larger reduction in EQ-5D index score, after controlling for age, gender, race, education, income, and BMI (p = 0.001) (Table 2)

Table 3. Multivariate linear regression for change in EQ-5D VAS score among adults with and without T2DM

Variables	Beta coefficient (SE)	p-value
T2DM vs. No DM	-0.762 (0.495)	0.12
Age, years (continuous, per 1 year)	-0.053 (0.015)	<0.0001
Women vs. men	1.078 (0.441)	0.015
Black vs. white	-0.556 (0.836)	0.51
Other race vs. white	-2.481 (1.467)	0.09
BMI, kg/m^2	0.087 (0.030)	0.004
Income (referent: <$22,500)		
$22,500 – $39,999	0.497 (0.641)	0.44
$40,000 – $59,999	0.026 (0.676)	0.97
$60,000 – $89,999	-0.687 (0.691)	0.32
>$89,999	0.357 (0.709)	0.61
Education (referent: high school degree)		
Some high school	0.208 (1.137)	0.85
Some college	0.153 (0.553)	0.78
College graduate	0.512 (0.653)	0.43
Graduate courses/degree	0.170 (0.730)	0.82

- After controlling for demographic variables, change in EQ-5D VAS score did not differ between T2DM and No DM (Table 3)

Figure 2. Absolute change in EQ-5D index score among T2DM adults with and without diabetic complications



*p <0.01 for comparison of yes vs. no diabetic complications

- Among T2DM respondents, the decline in EQ-5D index score was significantly greater among those who had reported retinopathy or neuropathy over the 5 years, compared with respondents without these complications (p <0.01) (Figure 2)
- T2DM respondents with and without nephropathy had a numerically greater decline in EQ-5D index score over 5 years, but the difference was not statistically significant (p = 0.43)
- Among T2DM respondents, a decline in ED-5D VAS score was observed for those with and without diabetic complications, but the differences were not statistically significant (data not shown)

LIMITATIONS

- Diagnosis of diabetes and diabetic complications were self-reported and could not be validated with laboratory tests, medical records review, or administrative claims data. However, this bias is similar between the groups compared in this study
- Household panels, like the TNS NFO panel, tend to under-represent the very wealthy and very poor segments of the population and do not include military or institutionalized individuals

CONCLUSIONS

- Over a 5-year period, health status of respondents with T2DM declined significantly, compared with respondents with no diabetes, indicating that the burden of disease has a long-term detrimental impact on the quality of life of patients living with T2DM
- The significantly greater decline in EQ-5D index score in the T2DM group compared with respondents without diabetes is likely to impact utility scores for economic evaluations (less QALYs gained for T2DM), indicating lower QALYs for T2DM
- Greater decline in EQ-5D index score for T2DM respondents with reported retinopathy and neuropathy is likely to also impact utility scores in economic evaluations among individuals with T2DM; thus, the presence of diabetic complications should be accounted for in evaluation of the economic burden of T2DM

References

1. Grandy S et al. *Int J Clin Pract* 2008;62:562–568
2. Grandy S, Fox KM. *Health Qual Life Outc* 2008;6:18
3. Rabin R, de Charro F. *Ann Med* 2001;33:337–343
4. EuroQol Group. *Health Policy* 1990;16:199–208
5. Shaw JW et al. *Med Care* 2005;43:203–220
6. Pickard AS et al. *Health Qual Life Outcomes* 2007;5:70
7. Walters SJ et al. *Qual Life Res* 2005;14:1523–1532

LIST OF ABBREVIATIONS

BMI	Body mass index
DM	Diabetes mellitus
EQ-5D	EuroQol-5 dimensions questionnaire
HRQOL	Health-related quality of life
QALYs	Quality-adjusted life-years
SHIELD	Study to Help Improve Early evaluation and management of risk factors Leading to Diabetes
T1DM	Type 1 diabetes mellitus
T2DM	Type 2 diabetes mellitus
TNS NFO	Taylor Nelson Sofres National Family Opinion
VAS	Visual Analog Scale

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