HHS Public Access

Author manuscript

Qual Life Res. Author manuscript; available in PMC 2017 September 14.

Published in final edited form as:

Qual Life Res. 2013 August ; 22(6): 1245–1253. doi:10.1007/s11136-012-0245-0.

Ten-year change in self-rated quality of life in a type 1 diabetes population: Wisconsin Epidemiologic Study of Diabetic Retinopathy

Flavio E. Hirai,

Department of Epidemiology, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD, USA. Department of Ophthalmology, Federal University of Sao Paulo, Rua Botucatu, 820, Sao Paulo, Brazil

James M. Tielsch,

Department of International Health, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD, USA

Barbara E. K. Klein, and

Department of Ophthalmology and Visual Sciences, University of Wisconsin-Madison, Madison, WI, USA

Ronald Klein

Department of Ophthalmology and Visual Sciences, University of Wisconsin-Madison, Madison, WI, USA

Abstract

Purpose—To investigate a 10-year change of quality of life and associated factors in a population with type 1 diabetes.

Methods—The Medical Outcome Study Short Form-36 (SF-36) was administered in participants (n = 520) at the 1995–1996 and 2005–2007 examination phases of the Wisconsin Epidemiologic Study of Diabetic Retinopathy (WESDR). Physical (PCS) and mental (MCS) component summary scores were calculated. The associations between changes of quality of life and demographic, socioeconomic, and clinical factors were analyzed.

Results—PCS score decreased ($p < 0.001$) and MCS score increased ($p < 0.001$) after 10 years. The development of cardiovascular disease and the presence of limb amputation were associated with decrease in the PCS score. Those who were working and retired had increased MCS; those who were working and stopped had a decrease in the MCS score. Change in visual acuity and diabetic retinopathy status did not have a significant impact in health-related quality of life scores.

Conclusions—Our findings reinforce the necessity to make every attempt to decrease complications of diabetes in individuals with long-term type 1 diabetes in order to attenuate the diminished quality of life associated with those complications such as cardiovascular disease.

Correspondence to: Flavio E. Hirai.

Conflict of interest

The authors have no conflict of interest to disclose.

Change in employment status, likely due to development of these complications, was also strongly associated with poorer quality of life and suggests the benefits of preventing or decreasing complications to keep people with type 1 diabetes in the workforce.

Keywords

Epidemiology; Diabetes mellitus; Quality of life; Diabetic retinopathy

Introduction

Type 1 diabetes mellitus is a chronic disease, and its first diagnosis is usually done during childhood or adolescence. The ultimate goal of the treatment for type 1 diabetes has been to achieve metabolic control to prevent the development of macro- and microvascular complications. Intensive glycemic control reduces these complications, but increases patient burden and may affect quality of life [1, 2]. The burdens of intensive glycemic control include inconvenience, discomfort, costs, and at least occasional hypoglycemia. Further, development and progression of long-term complications (e.g., diabetic retinopathy and changes in visual acuity) may also affect quality of life in this population [2–4].

Most studies reporting data on quality of life in adult populations with type 1 diabetes were cross-sectional investigations including hospital-based patients [1, 5, 6]. Few studies have investigated longitudinal, long-term associations of clinical (e.g., development of microvascular complications) and nonclinical (e.g., socioeconomic status) factors with quality of life in type 1 diabetes [4, 7, 8].

While there are prevalence data concerning some of these problems, incidence data add the important temporal nature of the association and thus permit the examination of long-term effects of diabetes, its treatment, and its complications on subsequent quality of life. The Wisconsin Epidemiologic Study of Diabetic Retinopathy (WESDR) is an ongoing prospective cohort study that provides the opportunity for an exploratory study to investigate the possibility of such longitudinal changes of several clinical and nonclinical factors over a 10-year interval in persons with type 1 diabetes.

Research design and methods

Study population

The WESDR involved 2,990 individuals with types 1 and 2 diabetes who received their medical care in an 11-county area in southern Wisconsin initiated in 1979–1980 [9, 10]. All individuals who were diagnosed before 30 years of age were categorized as the “younger-onset” group (N = 1,210). This group is considered to have type 1 diabetes based on C-peptide testing. Of this group, 996 participated in the baseline examination (1980–1982), 891 in the 4-year follow-up (1984–1986), 765 in the 10-year follow-up (1990–1992), 654 in the 14-year follow-up (1995–1996), 567 in the 20-year follow-up (2000–2001), and 550 in the 25-year follow-up (2005–2007). Refusal rates were low for all examinations [11–14]. The analyses in this paper are based on the subjects who participated in both the 1995–1996 and the 2005–2007 examinations.

Procedures

Examinations followed standardized protocols and consisted of a clinical examination that included measurements of blood pressure, height, and weight. An ophthalmic evaluation included measurement of best-corrected visual acuity after refraction, anterior segment biomicroscopy, tonometry, and fundoscopy after pupil dilation. Stereoscopic color fundus photographs of 7-standard fields were taken to assess diabetic retinopathy status and other fundus abnormalities [15]. While pupils were being dilated, participants were asked questions by trained interviewers regarding their current and past medical conditions, use of medications, information about cigarette smoking, and alcohol consumption. Laboratory tests included blood levels of glycosylated hemoglobin measured using a microcolumn technique [16], and total and high-density lipoprotein cholesterol concentrations were measured in EDTA plasma using a cholesterol oxidase method (Roche Diagnostics Corporation, Indianapolis, IN). Urine samples were tested for the presence of gross proteinuria using a reagent strip (Labstix, Bayer, Germany).

Health-related quality of life was assessed using the Medical Outcomes Study (MOS) Short Form 36 Health Survey (SF-36)[17]. Participants answered the questions during regular study visits. Higher scores indicate better health status. The SF-36 has eight subscales that were analyzed in this study: physical functioning (PF), physical role (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), emotional role (RE), and mental health (MH). All SF-36 measures were transformed to a score ranging from 0 to 100. In addition, the physical (PCS) and mental (MCS) component summary measures were calculated [18] and standardized to a US population with a mean of 50 and standard deviation of 10. The SF-36 questionnaire was administered only in the 1995–1996 and 2005–2007 examinations.

Definitions

Age was defined as age at the 1995–1996 examination. Duration of diabetes was the time between diagnosis and the 1995–1996 visit. Education was defined as the number of years of school completed. Employment was categorized into “full/part-time workers,” “retired,” “not working,” and “other” (e.g., students or homemakers) at the time of examination. Individuals were asked whether they had smoked more than 100 cigarettes in their lives. If they answered positively, the number of cigarettes per day and the number of years smoked were recorded. Pack years smoked at each visit were calculated (one pack year was equivalent to smoking one pack per day for a year) at each examination. Alcohol consumption was calculated in ounces per day. Body mass index (BMI) was calculated using the following formula: $\text{weight(kg)}/[\text{height(m)}]^2$. Individuals also answered the questions regarding their marital status, health insurance, insulin use, frequency of hypoglycemic reactions, and episodes of ketoacidosis. Subjects were asked to describe their usual physical activity as “sedentary,” “moderate,” or “strenuous.”

Nephropathy was defined as history of kidney transplant, being on renal dialysis, or positive gross proteinuria (defined as urine concentration of ≥0.30 g/l measured by reagent strip). Neuropathy was defined as history of numbness or tingling in hands or feet, loss of sensation in hands or feet, and/or decreased ability to feel the hotness or coldness of things touched.

Limb amputation was assessed by questionnaire or direct observation. Cardiovascular disease was defined as history of angina, myocardial infarction, coronary bypass surgery, and/or stroke.

Diabetic retinopathy (DR) was graded using the fundus photographs according to a modified Airlie House classification scheme [19]. Severity class for an individual was assigned based on the grade in the worse eye. The categories were “no retinopathy” (level 10), “mild nonproliferative DR” (level > 10 and ≤37), “moderate NPDR” (level > 37 and ≤47), “severe NPDR” (level>47 and<60), and “proliferative DR” (level ≥ 60).

For visual acuity, the Early Treatment Diabetic Retinopathy Study (ETDRS) protocol was used to determine best-corrected visual acuity [20]. The total number of letters read was recorded.

Changes between 1995–1996 and 2005–2007

Changes in quality of life scores and other continuous variables such as glycosylated hemoglobin, BMI, history of smoking and alcohol consumption, and visual acuity were defined as the difference between the 1994–1995 and 2005–2007 values. Employment was categorized as follows: “working at both visits” for those who remained full-or part-time employed between visits; “working and stopped” for those who lost their jobs during the period; “working and retired” for those who were working and retired between visits; “unemployed and started working” for those who were unemployed and started working during the period; “unemployed at both visits” for those who remained unemployed between visits; “retired” for those who remained retired; and “others” for those who did not change status (e.g., students or homemakers). Marital status was categorized as “married at both visits”; “married and not married” for those who became divorced or widowed during the period; “not married and married” for the ones getting married between visits; and “not married at both visits.” In order to account for incident and prevalent diseases, for each chronic condition (cardiovascular disease, nephropathy, neuropathy, and limb amputation), individuals were classified as “no disease” if they have not developed the condition during the interval; “onset before 95–96 visit” if they already had the condition (prevalent disease); and “onset after 95–96 visit” for those who developed disease between visits (incident disease).

In our regression models, change in visual acuity represented a change of 15 letters on the ETDRS chart, equivalent to a doubling of the visual angle. Diabetic retinopathy was regrouped into “None to Mild NPDR,” “Moderate to Severe NPDR,” and “Proliferative DR.” Changes in DR status would be classified in “No change,” “Improvement,” or “Progression” if individuals remained the same or moved from one category to another during the 10-year period.

Because all participants had the same change for age and diabetes duration between both visits, values for the 1995–1996 examination were used in our statistical analyses. Education did not change significantly during this period, and its value at 1995–1996 was also used in our analysis.

Statistical analysis

Results are first presented as mean ± SD and proportions. Comparisons of continuous variables between two visits were done with the Wilcoxon's signed-rank test, and categorical variables were compared with the chi-square and McNemar's tests.

We calculated the effect size of each SF-36 subscale, PCS, and MCS as suggested by Norman et al. [21] by dividing differences in scores by the baseline standard deviation (SD).

PCS and MCS were chosen as our main outcome measures for this analysis. Linear regression models were built based on the "change score method" [22] using changes in the SF-36, PCS, and MCS as dependent variables. Unstandardized regression coefficients are reported, indicating how much change in the quality of life increased (positive coefficient) or decreased (negative coefficient) for every one-unit increase in the independent variable.

In the statistical analysis, we first performed a univariable analysis with each independent variable separately. Those that showed statistically significant association ($p < 0.05$) with the dependent variable were included in a first multivariable model. Then, we built a final full model adding to the first multivariable model those factors believed to be confounders based on the previous knowledge about quality of life in people with type 1 diabetes. Because of potential correlation between variables representing long-term complications of diabetes, we analyzed complications such as nephropathy, neuropathy, limb amputation, and retinopathy in separate models and then together in a final model for PCS and MCS. We also analyzed visual acuity and retinopathy status in separate models and together in the same model due to possible multicollinearity. Interactions were tested in our analysis by adding multiplicative terms in our regression models and also through stratification. A p value <0.05 was considered to be statistically significant. Analyses were performed using Stata v. 10 (College Station, Texas).

The Institutional Review Board of the University of Wisconsin, Madison, approved the study (M-2005-1047), and all participants provided consent. This research followed the tenets of the Declaration of Helsinki.

Results

Five hundred and twenty individuals participated in both (1995–1996 and 2005–2007) visits and presented complete data regarding the SF-36 questionnaire. There were no significant differences in age, sex, physical activity, smoking, visual acuity, and presence of long-term complications between those included and excluded from the analysis due to incomplete data. There were higher proportions of individuals who were not married, not working either full- or part-time, and drinking less alcohol among those excluded.

We also analyzed characteristics at the baseline examination of those who participated in the 25-year follow-up, those who did not participate because they could not be located or they refused, and those who had died. With the exception of less education, there were no significant differences in characteristics of those who participated compared with those who survived but did not participate. Persons with younger-onset type 1 diabetes who had died

were older and had longer duration of diabetes, higher glycosylated hemoglobin, more proteinuria, higher systolic blood pressure, greater BMI, more pack years smoked, more severe retinopathy, and poorer visual acuity than those who participated.

Table 1 shows the characteristics of the study population in both visits. The mean age at the 2005–2007 examination was 49.2 ± 9.4 years, 49.3 % of whom were males. A significant proportion of people either retired or stopped working by the time of the 2005–2007 examination. More of the cohort was using an insulin pump at 2005–2007 compared to 1995–1996 examination. A slightly higher proportion of people drinking alcohol was observed at the 2005–2007 visit, but fewer people were smoking. Levels of glycosylated hemoglobin and serum total cholesterol were lower, and serum HDL cholesterol levels and BMI were higher in the follow-up. The prevalence of microvascular and macrovascular complications increased after 10 years (Table 1).

Table 2 shows the SF-36 domain and summary scores at both examinations. PF, RP, BP, GH, RE, and the PCS scores had a statistically significant decrease during the study period. MH and the MCS scores had a statistically significant increase. Only two of the subscale differences over the period, VT and SF, did not reach statistical significance. Norms for the general US population were also included in this table [17]. In the 2005–2007 visit, all subscales, except for SF, RE, and MH, had lower scores than the general population. All values of effect size were < 0.5 in this population.

Tables 3 and 4 show results from our univariable and multivariable analyses for PCS and MCS, respectively. The univariate analysis showed that those with higher education had an increase in the PCS score. Individuals who stopped working had a decrease in the PCS score. Decrease in visual acuity and the presence of complications such as cardiovascular disease, neuropathy, and limb amputation also had negative impact in the physical component score. Because results did not significantly differ between models that included each complication separately and the full model, only the results from our full models for each component score were shown in the last column. When adjusting for potential confounders, higher education remained associated with increased PCS score while the presence of cardiovascular disease and limb amputation was associated with lower PCS.

Employment status had the most significant influence on the MCS in both uni- and multivariable analyses. Those who were working and stopped had lower MCS than those who were employed at both visits. Individuals who retired between both visits had higher MCS than those who remained working. Changes in visual acuity were associated with decrease in both PCS and MCS scores in the univariable analysis. However, both visual acuity and diabetic retinopathy status were not associated with changes in PCS and MCS scores if variables were included separately or together in the multivariable analysis.

Because lower limb amputation and vision loss are complications that may be directly related to unemployment, we tested the interaction between both variables combined with working status and the PCS and MCS. Individuals who lost a limb and stopped working scored approximately 10 points lower in the PCS than those who remained working and had no amputation ($p < 0.05$). No statistically significant changes were observed in the MCS.

Those who had a decrease in their vision and were not working did not score differently on the PCS and MCS from those who were working and did not have a change in their visual acuity status (data not shown).

Discussion

SF-36 subscales such as PF, RP, BP, GH, RE, and the PCS had lower scores, and MH and MCS had higher scores after 10 years. According to Norman et al. [21], effect sizes of <0.5 SD (half standard deviation) found in each subscale and both component scores indicate that changes might not be of clinical significance. This was probably reflected in the absence of significant changes in quality of life scores despite a remarkable increase in the prevalence of long-term complication such as nephropathy, neuropathy, and severity of retinopathy. However, some changes observed in our multivariable analyses should be considered.

In this cohort of people with type 1 diabetes with relatively long duration, the development of complications such as cardiovascular disease and limb amputation and change in working status at the 1995–1996 examination were associated with statistically significant changes in quality of life scores 10 years later. The presence of complications has been reported to be associated with poorer quality of life [2, 4, 23, 24]. In our study, individuals who had incident cardiovascular disease showed greater declines in the physical component score. In a study by Hart et al. [2], the presence of cardiovascular disease had the most pronounced negative influence on quality of life scores in general, and the presence of macrovascular and/or microvascular diseases had a lower impact on mental than physical health-related subscales. The same research group observed that higher diastolic blood pressure at baseline was associated with faster decrease in the PCS than the MCS in a 6-year longitudinal study of quality of life in individuals with type 1 diabetes [4].

One of the main strengths of WESDR has been its design to address questions related to diabetic retinopathy and vision. The presence of diabetic retinopathy has been related to lower overall health-related quality of life scores, but the impact has been even higher when accompanied by loss of visual acuity [3, 25–27]. In an 18-month follow-up multicenter trial for vision loss in patients with diabetic retinopathy, Matza et al. [3] showed that those who lost visual acuity by 10 or more letters had negative changes in all SF-36 domains. Although the decline of 3-lines of visual acuity was associated with negative changes in both PCS and MCS, the association was not statistically significant. Similarly, the progression of diabetic retinopathy to a worse status was not associated with significant changes in scores. One explanation for this finding might be that the mean visual acuity in the 2005–2007 was close to 20/20, indicating an excellent visual function status of this population despite the long-term diabetes.

It is believed that some characteristics that are more related to diabetes, such as intensive insulin treatment regimen and higher frequency of hypoglycemic events, could result in a poorer quality of life [1]. Investigators have shown better glycemic control to be associated with poorer quality of life [28], but others have not found this relationship [29]. None of these factors were associated with significant changes in quality of life scores in our multivariable models. A 10-year interval might have been too long to capture individual

perceptions about quality of life related to such dynamic changes (e.g., insulin treatment regimen) that usually have an impact in a much shorter period of time. In addition, because all participants in this study had at least 14 years of diabetes prior to 1995–1996 [13], they may have learned to adapt to frequent changes in daily routine imposed by the disease without significantly affecting their quality of life.

Change in employment status had the most important influence on the MCS changes in our study. Losing a job during this period was associated with negative changes in MCS even after controlling for other factors such as age, sex, education, and presence of comorbidities (e.g., cardiovascular disease). Retirement between the visits was associated with an increase in scores in MCS. Job stability is one of the main factors affecting self-esteem and emotional control [30]. Our results also showed, although not statistically significant, that those who became employed also had an increase in the MCS. Shih and Simon [31] showed that those who were unemployed presented 2 times higher odds of having severe psychological distress compared to those with full-time jobs in a survey of adults from the general population living in Los Angeles County. Employment status (i.e., unemployment) might be an intermediate variable between poor health and low PCS or MCS scores, resulting in an overadjustment in our multivariable models. We have examined this by rerunning our multivariable models without employment status in the model and reached the same conclusions (data not shown).

People with diabetes, low education level, and those who were not married have been found to have lower quality of life than more educated and married individuals [1, 32]. Neither education nor marital status was significant predictors of changes in health-related quality of life in our study.

In this study, we used the orthogonal scoring method to determine the PCS and MCS scores. Some authors support the use of oblique methods instead. We have performed one analysis using oblique methods to calculate the PCS and MCS, and the findings were consistent with that found using the orthogonal scoring methods (Hirai et al., unpublished data, June 15 2012), resulting in all conclusions being the same.

One of the limitations of our study is the fact that psychosocial measurements such as personality and self-esteem [33] or social support such as emotional and informational support were not measured. In addition, influences of short-term events such as frequency of hypoglycemic episodes and changes in treatment regimens between examinations might not have been captured due to the long period between the two examination phases. The availability of data in only two points in time also limits the ability to perform a more comprehensive longitudinal analysis and evaluate antecedent-consequent relations of change. Finally, this is a group of survivors, and if those who lost follow-up had worse health status and this was related to poorer quality of life, we could have underestimated the strength of our associations. Despite its limitations, the strengths of the WESDR should also be considered. The use of standard protocols such as the fundus photographs and standardized classification scheme for diabetic retinopathy allows detailed assessment of this condition decreasing chances of misclassification. The long follow-up and its population-based design provide an opportunity to study and understand these relationships among

individuals with long-term type 1 diabetes, and results can be extrapolated to larger populations in the United States with similar characteristics.

In summary, the development of complications, especially cardiovascular disease, had a significant influence on quality of life of individuals with type 1 diabetes. A minimal change in visual acuity was observed during the 10-year period, and it did not affect quality of life in this population. These findings reinforce the necessity of adequate glycemic and blood pressure control to prevent development of these complications in individuals with long-term type 1 diabetes. The changes in employment status, likely due to the development of these complications, were also strongly associated with poorer quality of life and suggest the benefits preventing complications and keeping people in the workforce.

Acknowledgments

The study was supported by the National Institutes of Health (Bethesda, MD) Grant No. EY06594 and EY016379 (R Klein, BEK Klein) and, in part, by Research to Prevent Blindness (R. Klein and BEK Klein, Senior Scientific Investigator Awards), New York (NY). The National Eye Institute provided funding for entire study including collection and analyses of data; RPB provided further additional support for data analyses. This research was also supported by the Mentor-based Post-doctoral Fellowship Award from the American Diabetes Association, Alexandria, VA (to R.K.).

References

1. Rubin RR, Peyrot M. Quality of life and diabetes. Diabetes Metab Res Rev. 1999; 15(3):205–218. [PubMed: 10441043]
2. Hart HE, Bilo HJ, Redekop WK, Stolk RP, Assink JH, Meyboom-de JB. Quality of life of patients with type I diabetes mellitus. Quality of Life Research. 2003; 12(8):1089–1097. [PubMed: 14651426]
3. Matza LS, Rousculp MD, Malley K, Boye KS, Oglesby A. The longitudinal link between visual acuity and health-related quality of life in patients with diabetic retinopathy. Health Qual Life Outcomes. 2008; 6:95. [PubMed: 18992161]
4. Hart HE, Redekop WK, Berg M, Bilo HJ, Meyboom-de JB. Factors that predicted change in health-related quality of life were identified in a cohort of diabetes mellitus type 1 patients. Journal of Clinical Epidemiology. 2005; 58(11):1158–1164. [PubMed: 16223659]
5. Jacobson AM. Quality of Life in Patients With Diabetes Mellitus. Semin Clin Neuropsychiatry. 1997; 2(1):82–93. [PubMed: 10320446]
6. Hahl J, Hamalainen H, Sintonen H, Simell T, Arinen S, Simell O. Health-related quality of life in type 1 diabetes without or with symptoms of long-term complications. Quality of Life Research. 2002; 11(5):427–436. [PubMed: 12113390]
7. Wandell PE, Brorsson B, Aberg H. Quality of life among diabetic patients in Swedish primary health care and in the general population: comparison between 1992 and 1995. Quality of Life Research. 1998; 7(8):751–760. [PubMed: 10097623]
8. Huang GH, Palta M, Allen C, LeCaire T, D'Alessio D. Self-rated health among young people with type 1 diabetes in relation to risk factors in a longitudinal study. American Journal of Epidemiology. 2004; 159(4):364–372. [PubMed: 14769640]
9. Klein R, Klein BE, Moss SE, DeMets DL, Kaufman I, Voss PS. Prevalence of diabetes mellitus in southern Wisconsin. American Journal of Epidemiology. 1984; 119(1):54–61. [PubMed: 6691336]
10. Klein R, Klein BE, Moss SE, Davis MD, DeMets DL. The Wisconsin epidemiologic study of diabetic retinopathy. II. Prevalence and risk of diabetic retinopathy when age at diagnosis is less than 30 years. Archives of Ophthalmology. 1984; 102(4):520–526. [PubMed: 6367724]
11. Klein R, Klein BE, Moss SE, Davis MD, DeMets DL. The Wisconsin Epidemiologic Study of Diabetic Retinopathy. IX. Four-year incidence and progression of diabetic retinopathy when age at

diagnosis is less than 30 years. Archives of Ophthalmology. 1989; 107(2):237–243. [PubMed: 2916977]

12. Klein R, Klein BE, Moss SE, Cruickshanks KJ. The Wisconsin Epidemiologic Study of diabetic retinopathy. XIV. Ten-year incidence and progression of diabetic retinopathy. Archives of Ophthalmology. 1994; 112(9):1217–1228. [PubMed: 7619101]
13. Klein R, Klein BE, Moss SE, Cruickshanks KJ. The Wisconsin Epidemiologic Study of Diabetic Retinopathy: XVII. The 14-year incidence and progression of diabetic retinopathy and associated risk factors in type 1 diabetes. Ophthalmology. 1998; 105(10):1801–1815. [PubMed: 9787347]
14. Klein BE, Klein R, McBride PE, et al. Cardiovascular disease, mortality, and retinal microvascular characteristics in type 1 diabetes: Wisconsin epidemiologic study of diabetic retinopathy. Archives of Internal Medicine. 2004; 164(17):1917–1924. [PubMed: 15451768]
15. The Early Treatment Diabetic Retinopathy Study Group. ETDRS Coordinating Center. Early Treatment Diabetic Retinopathy Study: Manual of Operations. Department of Epidemiology and Preventive Medicine University of Maryland Baltimore; 1985.
16. Quick Step. Fast Hemoglobin Test System. 1981. p. 1-8.
17. Ware, JE., Kosinski, M., Gandek, B. SF-36 Health survey: manual & interpretation guide. Lincoln, RI: Quality-Metric Incorporated; 1993.
18. Ware, JE. Scoring Algorithms. In: Ware, JE.Kosinski, MA., Keller, SD., editors. SF-36 Physical and Mental Health Summary Scales: A User's Manual. Boston: The Health Institute, New England Medical Center; 1994.
19. Early Treatment Diabetic Retinopathy Study Research Group. Fundus photographic risk factors for progression of diabetic retinopathy. ETDRS report number 12. Ophthalmology. 1991; 98(5 Suppl): 823–833. [PubMed: 2062515]
20. Early Treatment Diabetic Retinopathy Study Research Group. Early Treatment Diabetic Retinopathy Study design and baseline patient characteristics. ETDRS report number 7. Ophthalmology. 1991; 98(5 Suppl):741–756. [PubMed: 2062510]
21. Norman GR, Sloan JA, Wyrwich KW. Interpretation of changes in health-related quality of life: the remarkable universality of half a standard deviation. Medical Care. 2003; 41(5):582–592. [PubMed: 12719681]
22. Allison PD. Change scores as dependent variables in regression analysis. Sociological Methodology. 1990; 20:93–114.
23. Wikblad K, Leksell J, Wibell L. Health-related quality of life in relation to metabolic control and late complications in patients with insulin dependent diabetes mellitus. Quality of Life Research. 1996; 5(1):123–130. [PubMed: 8901375]
24. Aalto AM, Uutela A, Aro AR. Health related quality of life among insulin-dependent diabetics: disease-related and psychosocial correlates. Patient Education and Counseling. 1997; 30(3):215–225. [PubMed: 9104378]
25. Clarke PM, Simon J, Cull CA, Holman RR. Assessing the impact of visual acuity on quality of life in individuals with type 2 diabetes using the short form-36. Diabetes Care. 2006; 29(7):1506–1511. [PubMed: 16801570]
26. Hariprasad SM, Mieler WF, Grassi M, Green JL, Jager RD, Miller L. Vision-related quality of life in patients with diabetic macular oedema. British Journal of Ophthalmology. 2008; 92(1):89–92. [PubMed: 17584999]
27. Brown MM, Brown GC, Sharma S, Landy J, Bakal J. Quality of life with visual acuity loss from diabetic retinopathy and age-related macular degeneration. Archives of Ophthalmology. 2002; 120(4):481–484. [PubMed: 11934322]
28. Wikby A, Hornquist JO, Stenstrom U, Andersson PO. Background factors, long-term complications, quality of life and metabolic control in insulin dependent diabetes. Quality of Life Research. 1993; 2(4):281–286. [PubMed: 8220362]
29. The Diabetes Control and Complications Trial Research Group. Influence of intensive diabetes treatment on quality-of-life outcomes in the Diabetes Control and Complications Trial. Diabetes Care. 1996; 19(3):195–203. [PubMed: 8742561]

30. Judge TA, Bono JE. Relationship of core self-evaluations traits–self-esteem, generalized self-efficacy, locus of control, and emotional stability–with job satisfaction and job performance: a meta-analysis. Journal of Applied Psychology. 2001; 86(1):80–92. [PubMed: 11302235]

31. Shih M, Simon PA. Health-related quality of life among adults with serious psychological distress and chronic medical conditions. Quality of Life Research. 2008; 17(4):521–528. [PubMed: 18365766]

32. Glasgow RE, Ruggiero L, Eakin EG, Dryfoos J, Chobanian L. Quality of life and associated characteristics in a large national sample of adults with diabetes. Diabetes Care. 1997; 20(4):562–567. [PubMed: 9096981]

33. Hanestad BR. Self-reported quality of life and the effect of different clinical and demographic characteristics in people with type 1 diabetes. Diabetes Research and Clinical Practice. 1993; 19(2):139–149. [PubMed: 8472629]

Table 1

Characteristics of individuals who participated in both the 1995–1996 and 2005–2007 Wisconsin Epidemiologic Study of Diabetic Retinopathy examinations

	1995–1996 (*n* = 520)	2005–2007 (*n* = 520)	*p* value
Age (years)	39.2 ± 9.4	49.2 ± 9.4	< 0.001
Gender (male, %)	49.3	49.3	
Education			
Years in school	14.2 ± 2.5	14.7 ± 2.9	< 0.001
Employment (%)			< 0.001
Full/Part-time workers	83.7	68.3	
Retired	1.7	10.6	
Not working	7.6	16.3	
Other	7.0	4.8	
Marital status (married, %)	62.2	63.0	0.63
Health insurance (yes, %)	95.5	96.7	0.17
Insulin use (yes, %)	97.9	93.8	< 0.001
Times per day using insulin	2.31 ± 0.88	3.35 ± 1.06	< 0.001
Insulin pump (yes, %)	3.9	35.7	< 0.001
Physical activity (%)			0.88
Sedentary	33.8	34.3	
Moderate	56.3	57.4	
Strenuous	9.9	8.3	
Alcohol (%)			0.05
Never	3.6	2.2	
Former	20.6	19.5	
Current	75.8	78.3	
Smoking (pack years)	6.3 ± 15.6	7.3 ± 16.3	0.02
Smoking (%)			< 0.001
Never	60.9	59.4	
Former	23.8	28.8	
Current	15.3	11.8	
Glycosylated hemoglobin (%)	9.3 ± 1.4	7.6 ± 1.3	< 0.001
Diabetes duration (years)	25.1 ± 7.3	35.1 ± 7.3	< 0.001
Serum total cholesterol (mg/dl)	192.8 ± 40.3	167.1 ± 37.0	< 0.001
Serum HDL cholesterol(mg/dl)	50.9 ± 15.7	56.3 ± 17.1	< 0.001
Body mass index (kg/m^2)	26.6 ± 4.3	28.8 ± 5.6	< 0.001
Ketoacidosis within last year (yes, %)	8.1	6.1	0.24
Hypoglycemic events within last year (yes, %)	94.4	95.3	0.38
Frequency of hypoglycemic reactions (%)			0.70
1/day	4.3	4.5	
1–5/week	37.7	40.5	
1–3/month	33.2	36.8	

	1995–1996 (*n* = 520)	2005–2007 (*n* = 520)	*p* value
Less	24.8	18.2	
Nephropathy (yes, %)	23.9	48.6	< 0.001
Neuropathy (yes, %)	27.6	58.5	< 0.001
Limb amputation (yes, %)	2.1	6.6	< 0.001
Cardiovascular disease (yes, %)	7.8	25.7	< 0.001
Visual acuity (better eye, LogMAR)	−0.03 ± 0.16	0.04 ± 0.20	< 0.01
Diabetic retinopathy (%)			< 0.001
No retinopathy	2.6	2.2	
Mild NPDR	33.3	33.5	
Moderate NPDR	18.7	12.9	
Severe NPDR	2.4	0.5	
Proliferative DR	43.0	50.9	

Table 2

Mean health-related quality of life scores for each SF-36 domain at 1995–1996 and 2005–2007

	Norms, 1990**	1995–1996	2005–2007	Difference	*p* value	Effect size***
Physical functioning	84.15	85.7 ± 21.4	77.9 ± 26.8	−7.7 ± 20.6	< 0.001	0.35
Role physical	80.96	83.7 ± 30.7	75.1 ± 36.2	−8.6 ± 37.9	< 0.001	0.28
Bodily pain	75.15	77.0 ± 22.5	71.6 ± 23.8	−5.4 ± 23.4	< 0.001	0.24
General Health	71.95	65.9 ± 21.3	63.3 ± 24.2	−2.6 ± 18.8	< 0.01	0.12
Vitality	60.86	59.4 ± 19.4	58.4 ± 21.4	−0.9 ± 21.0	0.60	0.04
Social functioning	83.28	89.8 ± 17.2	88.2 ± 20.4	−1.6 ± 20.5	0.25	0.09
Role emotion	81.26	88.7 ± 26.6	82.6 ± 30.6	−6.1 ± 32.5	< 0.001	0.23
Mental health	74.74	75.3 ± 16.2	78.9 ± 16.6	3.7 ± 16.6	< 0.001	0.23
PCS*	50.00	49.6 ± 9.6	46.2 ± 11.1	−3.4 ± 8.9	< 0.001	0.35
MCS*	50.00	51.6 ± 8.3	52.9 ± 8.9	1.3 ± 9.2	< 0.001	0.15

* *PCS* physical component score, *MCS* mental component score

** Norms for the general US population, 1990 [17]

*** Effect size: (difference/SD at baseline)

Table 3

Uni- and multivariable analysis of change in physical component summary (PCS) scores between 1995–1996 and 2005–2007

	Univariable	Multivariable 1	Multivariable 2
R^2		0.1107	0.1835
Intercept		−1.66 **	−0.47
Age, per 1 year	−0.09 **	−0.02	−0.08
Sex, versus female *	−0.07		−0.75
BMI, per 1 kg/m^2 *	−0.39		−0.29
Education, per 1 year *	0.47 **	0.45 **	0.54 **
Employment, versus working at both visits			
Working and stopped	−4.54 **	−3.16	−2.89
Working and retired	−5.26 **	−4.27 **	−2.56
Unemployed and started working	0.68	1.66	3.75
Unemployed at both visits	1.73	3.54	6.74
Retired at both visits	1.88	5.04	3.61
Other	0.31	−0.10	−1.27
HbA1c, per 1 unit %	0.31		−0.16
Diabetes duration, per 1 year *	−0.11		0.01
Cardiovascular, versus no disease			
Onset before 95–96 visit	−2.58	−1.20	0.01
Onset after 95–96 visit	−3.34 **	−2.59 **	−3.55 **
Nephropathy, versus no disease			
Onset before 95–96 visit	−0.94		1.13
Onset after 95–96 visit	−1.47		−2.02
Neuropathy, versus no disease			
Onset before 95–96 visit	−1.98 **	0.30	−0.98
Onset after 95–96 visit	−2.66 **	−0.39	0.11
Amputation, versus no disease			
Onset before 95–96 visit	−4.68 **	−7.24 **	−9.22 **
Onset after 95–96 visit	−1.75	0.72	−2.64
Visual acuity, per 3-line decrease	−2.59 **	−2.11	−1.79
Diabetic retinopathy, versus no change			
Improvement	2.42		2.05
Progression	−0.65		−1.49

Unstandardized regression coefficients

Univariable univariable analysis

Multivariable 1 included only statistically significant variables in the univariate analysis

Multivariable 2 included all variables in the model

*1995–1996 visit values

**$p < 0.05$

Table 4

Uni- and multivariable analysis of change in mental component summary (MCS) scores between 1995–1996 and 2005–2007

	Univariable	Multivariable 1	Multivariable 2
R^2		0.0923	0.1363
Intercept		1.30 **	1.08 **
Age, per 1 year	−0.01		0.02
Sex, versus female *	−0.57		−0.68
BMI, per 1 kg/m^2 *	0.26		0.33
Education, per 1 year *	−0.01		−0.24
Employment, versus working at both visits			
Working and stopped	−4.00 **	−4.03 **	−4.95 **
Working and retired	5.83 **	6.32 **	6.37 **
Unemployed and started working	4.99	5.88	7.81
Unemployed at both visits	2.62	2.33	0.82
Retired at both visits	−3.22	−5.47	−7.40
Other	−0.75	−0.54	0.46
HbA1c, per 1 unit %	0.06		−0.01
Diabetes duration, per 1 year *	−0.01		−0.01
Cardiovascular, versus no disease			
Onset before 95–96 visit	0.06		−0.85
Onset after 95–96 visit	−0.03		−0.22
Nephropathy, versus no disease			
Onset before 95–96 visit	−0.34		−0.63
Onset after 95–96 visit	−1.18		0.01
Neuropathy, versus no disease			
Onset before 95–96 visit	−0.17		−0.77
Onset after 95–96 visit	−1.49		−1.40
Amputation, versus no disease			
Onset before 95–96 visit	4.63		1.68
Onset after 95–96 visit	2.69		0.77
Visual acuity, per 3-line decrease	−2.08 **	−2.50 **	−1.69
Diabetic retinopathy, versus no change			
Improvement	−1.70		1.36
Progression	0.73		1.06

Unstandardized regression coefficients

Univariable univariable analysis

Multivariable 1 included only statistically significant variables in the univariate analysis

Multivariable 2 included all variables in the model

* 1995–1996 visit values

** $p < 0.05$