Delft N, Allert G, Ostroga-Petersen G, Pokorny D, Böhm BO, Brückel J, Kächele H (2004) Investigation of Compliance regarding the Self-Care Behaviors of Type 1 Diabetics. submitted

Investigation of Compliance regarding the Self-Care Behaviors of Type 1 Diabetics

N. von Delft[1], G. Allert[1], G. Ostroga-Petersen[1],
D. Pokorny[1], J. Brückel[2], B.O. Böhm[2], H. Kächele[1]

[1]Department of Psychotherapy and Psychosomatic Medicine, University of Ulm, Germany

[2]Department of Internal Medicine I, Section of Endocrinology, University of Ulm, Germany

Correspondendent Author:
Dr. Nina von Delft
Baaderstraße 53, D-80469 München
Tel/Fax: +49 89 20 20 64 04
e-mail: nina.vondelft@t-online.de

Keywords:
type 1 diabetes, self-care behavior, compliance**,** life-satisfaction, Freiburger Personality Inventory, FPI-R

Abstract:
Background: The factors influencing the self-care behavior and their relation to metabolic control of type 1 diabetics are not well understood. Some previous studies have viewed compliance as a single behavioral trait of a patient. We tried to use a more differentiated approach by measuring a substantial number of different aspects of self-care behavior.
Methods: We analysed the responses of 180 patients with type 1 diabetes (aged 18 to 65 years) to questions with regard to compliance and self-care activities, and measured their glycosylated hemoglobin A1c (HbA1c). Patients also answered the (revised) Freiburg Personality Inventory (FPI-R).
Results: Higher levels of HbA1c correlated with lower values of the FPI-R scale „life-satisfaction„ (1). Both were more likely to occur among females than males (2) and patients with lower education levels (3). Older patients had higher HbA1c (4). Patients with higher HbA1c and lower life-satisfaction had more long-term complications (5), dietary problems (6), insulin injections per day (7) and visited a physician more frequently (8). A high HbA1c was more likely to occur among patients that tended to omit insulin injections (9) or blood glucose testing (10), or did not test it at all (11). Lower life-satisfaction tended to occur for patients that did not excercise (12) and regarded themselves insufficiently well-informed about their disease (13).
Conclusions: Our results underline the importance of taking a differentiated view of the concept of compliance, which relates, i.a., to both metabolic control and life-satisfaction. By including the latter in our analysis too, we realized certain problems of self-care behavior which would have gone unnoticed, if HbA1c had been used as sole indicator.

Introduction

Diabetes mellitus, with a prevalence of about 5% [1] is one of the most common chronic diseases in Germany. In contrast to most other diseases, the patients affected by diabetes have definite ways and means to influence their prognosis and the course of their disease. Adequate therapy is able to compensate the symptoms, and as shown in the DCCT [2], intensive insulin treatment of type 1 diabetes may substantially reduce and/or delay the development and progression of microvascular and neuropathic complications. However, the need for a life-long therapy causes both medical and psychological problems.

Compliance with medical advice is known to be poor in chronic diseases and in complex treatment regimes, so it is not surprising that self-care problems occur among diabetic patients [3]. Describing patients only as compliant or noncompliant as if compliance were a traitlike characteristic or regarding ‘compliance‘ as a unitary concept is therefore of limited value, and research should rather be based upon reliable assessments of the current level of each type of self-care behavior [3].

There is also increasing evidence that different diabetes regimen behaviors are relatively independent of one another and consequently global ratings or composite scores of compliance may not adequately reflect the complexity of a diabetes regimen [4]. Measuring diabetes regimen compliance therefore requires a multicomponent measuring strategy which incorporates medical, social and psychological aspects.

In this study we investigated *self-care behaviors* as one of the outcomes of such a multicomponent measuring strategy [where the term *self-care behaviors*, rather than *compliance* is used to remind the reader that we are studying patients, reports of their regimen and regimen behavior.]

The goal of studies on self-care behaviors of patients is to help their health-care providers to optimize therapy in order to achieve not only a proper metabolic control but also a high quality of life. Due to the increased scope of possible medical treatments, it is no longer adequate to use purely somatic or biological criteria such as certain laboratory results or mortality rates to judge the success of a specific therapeutic regimen. Instead, there have been increasing calls, such as the St. Vincent-Declaration in 1990 [5], to consider also the effects of therapeutic strategies on the subjective quality of life of the patient [6].

A patient diagnosed to be diabetic has to alter his lifestyle sometimes substantially in certain aspects. This not only involves the integration of therapy into daily life, but may also imply that the patient has to relinquish certain career options or even the career itself. Patients whose quality of life is reduced by these changes will in general find it more difficult to adhere to a therapeutic regimen than those that are able to maintain a high quality of life. Patients that, in the long run, are unable to integrate the therapeutic regimen into their daily routine will experience a worsened metabolic control and hence will be at

increased risk to suffer long-term complications. If, on the other hand, the disease and its treatment influence the patient‘s daily life to such an extent that spontaneity is lost and important goals in life can not be realized, this too will reduce the perceived quality of life and may lead to psychological complications such as depression, etc.. Evidently, a balanced approach is essential, with negotiation of common goals between patient and health care provider.

In the present study, we investigated the self-care behaviors of type 1 diabetics with respect to the following aspects of a diabetes regimen: insulin injections, diet, exercise, information about diabetes (e.g. feeling sufficiently „informed„), number of visits to a physician and frequency of blood glucose testing. A better understanding of these factors should be helpful for the identification of high-risk patients and for the development of appropriate countermeasures such as psychotherapy and educational support.

Subjects and Methods

Design, Population and Sampling Procedure

We obtained our results [7] within the context of a study which primarily investigated the comorbidity of type 1 and type 2 diabetes and eating disorders. However, since it is widely accepted that eating disorders can have many causes, we analyzed not only diabetes-specific questionnaires and –scales (DIA-MED I and DIA-MED-Self, described below), but also studied coping behavior, socio-economic conditions and personality traits, using a set of questionnaires that has been implemented in a German multi-center study on the psychodynamic treatment of eating disorders [8]. 253 patients aged between 18 and 65 were questioned at the University Ulm in the years 1994/1995. Patients that suffered from dementia or serious organic diseases which were not consequences of diabetes mellitus, or that had an insufficient command of the German language, were excluded from the study.

Data Collection

Patients of the Department of Internal Medicine I of the University of Ulm were subjected to a structured interview on diabetes mellitus (Dia-MED I). On the same day, their HbA1c, the most widely accepted measure of diabetes control, was determined by affinity-chromatography (in our laboratory, standard HbA1c values are between 4.3 and 6.1%). Subsequently the patients received a packet of questionnaires, including the Diabetes-Questionnaire (Dia-MED Self) and the (revised) Freiburg Personality Inventory (FPI-R). The recruitment of patients and data collection were organized and performed during a 12-month period by a team of 7 post-graduate medical students of the University of Ulm [1].

[1] Michaela Bürger, Nina von Delft, Susanne Friedrichs, Jutta Markert, Isabella Schneider, Matthias Wagner, Heike Wiedemann

Interview and Questionnaires

The interview Dia-MED I and the Dia-Med Self questionnaires were developed at the Department of Psychotherapy and Psychosomatic Medicine in collaboration with the Department of Internal Medicine I of the University of Ulm. Dia-MED I contained i.a. questions on symptomatics, complications and compliance. Dia-MED Self contained questions i.a. on sociodemographic factors, self-care activities to regulate the blood glucose, forgetting medication and on dietary matters. The construction of this test is based mainly on the clinical experience of diabetologists, and no independent measures of its reliability are available. Although patients were asked to complete the FPI-R [9] in its entirety, for the purposes of this paper we analyzed only the FPI-RI scale „life-satisfaction„.

Statistical Analyses

Statistical analyses were performed on the subsample of n=180 patients suffering from Type 1 diabetes at least 1 year. The goal of this study was to investigate dependency between the disease-related self-care behavior, metabolic control, sociodemograhic factors and the scale "life-satisfaction" of the Freiburg Personality Inventory (FPI-R). Influence factors were investigated in the sake to improve prediction possibilities for self-care behavior and metabolic control. We had to deal with a mixture of dichotomous, ordinal and interval scaled variables. For the two group comparison following measures and tests were applied, depending on the scale of the investigated variable: effect size ES and the two-group t-test for an interval variable, Cureton`s biserial rank correlation coefficient and Mann-Whitney U-test for an ordinal variable, Yule`s Q and Fisher test for a dichotomously variable. The relationship of two at least ordinal variables was examined by the Spearman‘s rank correlation coefficient.

Confirmatory hypotheses were examined using the one-sided significance level 0.05, other exploratory questions using the two-sided significance level. Confirmatory hypotheses concern self-care behavior-variables, exploratory hypotheses concern the influence of sociodemograhic variables, disease related variables and health-related behavior.

The reported bivariate results were examined with respect to influence of third variables, using techniques like partial correlations, analysis of variance and covariance and log-linear models in three-way contingency tables. This statistical discussion – not shown here – confirmed the stability of presented results.

Statistical analyses were performed using the statistical software package BMDP [10].

Results

Table 1. Patient characteristics of 180 type 1 diabetes patients.

Gender	n	(%)
Male	100	(55.6)
Female	80	(44.4)

	mean	SD
Age, years	38.1	11.9

	mean	SD
Duration of Type 1, years	14.4	10.0
Body Mass Index kg/m2	23.3	2.7
HbA1c[2], % (n=177 patients)	7.6	1.3

Diabetic complications	n	(%)
Retinopathy	55	(30.6)
Neuropathy	31	(17.2)
Nephropathy	22	(12.2)

SD: Standard deviation

%: frequency

n: number

[2] Standard HbA1c value of our laboratory: 4,3-6,1%.

Table 2 Correlations involving the variables HbA1c and life-satisfaction (FPI-R1).

	n	HbA1c			n	Life-satisfaction		
1. Life-satisfaction	155	r	–0.22	**				
2. Sociodemographic variables								
Sex (female/male)	177	ES	+0.41	**	157	C	–0.21	*
Education level	156	r	–0.31	***	153	r	+0.24	**
Age	180	r	+0.16	*	157	r	–0.55	
						n.s.		
3. Self-care behavior-items								
Frequent problems with diet	120	r	+0.26	**	117	r	–0.20	*
Insulin injections per day	172	r	+0.21	**	153	r	–0.18	*
Number of visits to physician per year	166	r	+0.24	***	146	r	–0.25	**
Omitted insulin injections	142	r	+0.20	**	141	r	+0.02	
						n.s.		
Omitted glucose testing	139	r	+0.26	**	138	r	+0.11	
						n.s.		
No glucose testing at all	177	ES	+1.83	*	157	C	–0.69	
						n.s.		
No exercise at all	155	ES	+0.04	n.s.	153	C	–0.19	*
Insufficiently-informed about diabetes	160	ES	+0.03	n.s.	157	C	–0.26	*

n: sample size

r: Spearman,s rank correlation coefficient and its significance

C: Cureton‘s biserial rank correlation coefficient and Mann-Whitney U-Test

ES: Effect size for two groups and t-test

Significance level: * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$, two-sided and for self-care behavior items: one-sided probability level.

Table 1 shows the sociodemographic and disease-related data of 180 type-1 patients, with an average age of 38.1 years. Of these 100 (55.6%) were men and 80 (44.4%) were women. Mean duration of diabetes was 14.4 (±10.0) years, mean HbA1c was 7.6 (±1.3). Retinopathy was the complication with the highest prevalence (30.6%), followed by neuropathy (17.2%) and nephropathy (12.2%).

Table 2 summarizes various correlations of parameters with the variables HbA1c and life-satisfaction. There is a negative correlation between HbA1c and life-satisfaction ($p < 0.01$). This manifests itself in the fact that variables which correlate positively with HbA1c correlate negatively with life-satisfaction, and vice versa.

Regarding sociodemographic factors, higher HbA1c values and lower life-satisfaction was more likely to occur ($p < 0.01$ and 0.05, respectively) among females than males, and among patients with lower education levels ($p < 0.001$ and 0.01, respectively). Moreover, older patients had higher HbA1c ($p < 0.05$), but there was no significant correlation between age and life-satisfaction.

Analysis of disease related variables showed that higher HbA1c and lower life-satisfaction correlated with a higher number of insulin injections per day ($p < 0.01$ and 0.05, respectively), and with a higher frequency of visits to a physician per year ($p < 0.001$ and 0.01, respectively).

Regarding self-care behavior, higher HbA1c and lower life-satisfaction correlated with more dietary problems ($p < 0.01$ and 0.05, respectively). However, not all self-care items correlated significantly with *both* HbA1c and life-satisfaction: On the one hand, patients that had indicated that they were likely to omit insulin injections ($p < 0.01$) and glucose testings ($p < 0.01$), or that they did not test their glucose at all ($p < 0.05$), were more likely to have a higher HbA1c (the difference was not statistically significant). On the other hand, patients that did not exercise ($p < 0.05$) or who regarded themselves insufficiently well-informed about their disease ($p < 0.05$), were likely to have a lower life-satisfaction (again, the difference was not statistically significant).

Finally, we noted some differences between patients practising intensified insulin therapy and patients on conventional insulin therapy: 149 (82.8%) patients had an intensive treatment, i.e. at least three insulin injections and at least four glucose tests per day; 31 (17.2%) were on conventional treatment (one or two insulin injections per day and at least one glucose test per day). Patients following the intensive treatment had a mean HbA1c of

7.7±1.3%, which, somewhat unexpectedly, is significantly higher than the value 7.2±1.1% for patients practising the conventional treatment (ES: 0.44, $p < 0.05$).

Discussion

Our result that metabolic control was poorer in women than in men has been found in other studies before [11-13], though the reasons are not yet clear. One possible reason could be that women are less confident in their ability to manage their diabetes, as found by Rubin und Peyrot [14]. Our result that women had less life satisfaction than men has been observed in previous studies [15-17]. Gender seems to be a risk factor for depression, with women twice as likely as man [18].

A negative correlation between HbA1c and the level of education has been described before [19,20]. A lower level of education could make it more difficult for a patient understand completely the given information about diabetes, and could moreover imply that the patient‘s social environment is less supportive in coping with a complicated situation. Such patients might also be less willing to deal with their disease in a rational way, might be less independent and less flexible when adjusting to the new situation, and perhaps in general have a lower expectation regarding their ability to cope with adversity and the level of life satisfaction they strive for. Indeed, we found a significant correlation between lower education level and lower life satisfaction.

Correlations between periods of depression and high HbA1c [21,22] and lower compliance [22] have been reported before. As possible explanations, Sachs et al. [22] have suggested, first, possible indirect effects of psychosocial variables, e.g. coping ability, on self-care behavior, and second, that there could be a direct physiological link between depression and HbA1c, e.g. through the induction of hyperglycemic phases by an elevated plasmacortisol level.

According to our results, higher HbA1c and lower life-satisfaction also correlated with more dietary problems, particularly among patients with intensive treatment. Tewes et al. [23] have reported a similar result for typ-2 diabetics, who experienced the necessity to follow a strict diet as a severe restriction on their quality of life.

Our result that patients with higher HbA1c and lower life satisfaction visited their doctor more often could be related to the fact they had less confidence in their own ability to follow the therapeutic regimen.

We found that a higher number of insulin injections and glucose testings in our sample did not imply a lower HbA1c; instead, this might reflect an adaptation of treatment with more frequent testings/injections when satisfactory metabolic control is not reached by simple regimens. We also observed that the less often these measures were omitted, the lower the HbA1c level was.

The following factors should be regarded when interpreting these results: Our sample consisted of patients of an outpatient clinic of an universitary hospital, i.e. our patients may not be representative for a population of type 1 diabetics but may rather be a subset with difficult metabolic control or more prevalent diabetic complications. This is also evident from their higher frequency of visits to a physician. In other words, in our study a high number of insulin injection is, in general, indicative of problems in attaining good HbA1c levels, an increased need for patient care and an increased rate of complications. Moreover, the samples of intensively and conventionally treated patients differed in size (148 vs. 29), though this difference is here not statistically significant. Finally, a possible reason why conventionally treated patients reported a better quality of life might be, that their risk behavior could be increased.

Patients who were likely to omit their insulin injections and glucose testings, or who did not test their glucose at all, were more likely to have a higher HbA1c. As expected, this underlines the importance of performing insulin injections and glucose testings, the pillars on which the therapy of diabetes rests.

Patients that did not exercise were likely to have a lower life-satisfaction. Regular exercise is known to have an antidepressant, mood-elevating effect and can improve someone,s self-esteem, which would have a positive effect on chronically ill patients.

Patients who regarded themselves to be insufficiently well-informed about their disease were likely to have a lower life-satisfaction. Even though their HbA1c was not significantly higher, their subjective lack of information seemed to promote a feeling of insecurity among such patients, so that they were generally less content.

Finally, it should be mentioned that the scale „life satisfaction„ from the (revised) Freiburg Personality Inventory is probably not the most appropriate tool for measuring quality of life. More specific tools do exist, such as the "Diabetes Quality of Life Scale" (DQOL) of Jacobson et al. [24], which measures the diabetes-related quality of life of type-1 diabetics, the QLQ-C30 of the EORTC (25) the "Well-being and Treatment Satisfaction Scale" of

Bradley and Lewis [26], which is designed to capture the life-satisfaction of type-2 diabetics, or the "Symptom Checklist-90R", which was used in the DCCT to measure quality of life. However, since our study already included a large number of other questionnaires, it was not possible to incorporate any of the above tools additionally. Nevertheless, the scale „life-satisfaction„ showed sufficiently many significant correlations with various aspects of self-care behavior, that in our opinion it would be meaningful to check our results with some of the alternative tools just mentioned, and to eventually incorporate them into the design and optimization of future diabetes therapies.

To conclude, our results underline the importance of taking a differentiated view of the notion of compliance, which relates, i.a., to both metabolic control and life-satisfaction. By including the latter in our analysis too, we uncovered certain problems of self-care behavior which would have been unnoticed, if HbA1c had been used as the only indicator. The present results could serve as points of departure for further in depth studies of causal connections between various aspects of self-care behavior and the HbA1c, as well as sociodemographic and psychological factors. In particular, in the future it might be interesting to focus more on the risk groups identified above.

References

1 Berger M: Epidemiologie des Diabetes mellitus. in: Berger M (ed.): Diabetes mellitus. München, Wien, Baltimore, Urban Schwarzenberg, 1995, pp 15-22.

2 The Diabetes Control and Complications Trial Research Group: The effect of intensive treatment of Diabetes on the development and progression of long-term complications in Insulin-dependent Diabetes mellitus. New Engl J Med 1993; 329: 977-986.

3 Peveler RC, Davies BA, Mayou RA, Fairburn CG, Mann JI: Self-care behavior and blood glucose control in young adults with type 1 diabetes mellitus. Diabet Med 1993, 10:74-80.

4 Johnson, SB, Freund A, Silverstein J, Hansen CA, Malone J: Adherence-health status relationships in childhood diabetes. Health Psychol 1990, 9: 606-631.

5 Diabetes Care and research in Europe: The Saint Vincent Declaration. Diabet Med 1990 May; 7 (4): 360.

6 Hermanns N, Kulzer B: Die Messung von Wohlbefinden bei Diabetikern: Evaluation des Wohlbefinden-Fragebogens von Bradley. in: Kohlmann C-W, Kulzer B (ed.): Diabetes und Psychologie; diagnostische Ansätze. Bern, Huber, 1995, pp 34-50.

7 von Delft N: Untersuchungen zur Compliance bzw. zum Selbstbehandlungsverhalten bei Diabetikern, Medizinische Dissertation Universität Ulm, 1999.

8 Kächele H, Kordy H, Richard M: Therapy amount and outcome of inpatient psychodynamic treatment of eating disorders in Germany: Data from a multicenter study. Psychotherapy Research 2001, 11: 239-257.

9 Fahrenberg J, Hampel R, Selg H: Freiburger Persönlichkeitsinventar (FPI), Revidierte Fassung des FPI-R und teilweise geänderte Fassung FPI-A1.5. Ergänzte Auflage. Göttingen, Toronto, Zürich, Hogrefe, 1989.

10 Dixon WJ (Ed.): BMDP Statistical Software Manual. Vol. 1,2. Los Angeles, Oxford, Berkeley, University of California Press, 1992.

11 Rubin RR, Peyrot M: Men and diabetes: Psychosocial and behavioral issues. Diabetes Spectrum 1998; 11: 81-87.

12 Glasgow RE, McCaul KD, Schafer LC: Self-care behavior and glycemic control in Type 1 diabetes. J Chron Dis 40: 399-412 (1987)

13 Schafer LC, Glasgow RE, McCaul HD, Dreher M: Adherence to IDDM regimens: Relationship to psychosocial variables and metabolic control. Diabetes Care 1983; 6: 493-498.

14 Rubin RR, Peyrot M: Men and diabetes: Psychosocial and behavioral issues. Diabetes Spectrum 1998, 11: 81–87.

15 Lustman PJ, Griffith LS, Clouse RE, Cryer PE: Psychiatric illness in diabetes relationship to symptoms and glucose control. J Nerv Ment Dis 1986, 174: 736-742.

16 Lustman PJ, Griffith LS, Clouse RE: Depression in adults with diabetes: Results of 5yr follow up study. Diabetes Care 1988, 11: 605–612.

17 Lloyd CE, Matthews KA, Wing RR, Orchard TJ: Psychosocial factors and compliacations of IDDM. The Pittsburgh Epidemiology of Diabetes Compliacations Study VIII. Diabetes Care 1992, 15: 166–172.

18 Peyrot M, Rubin RR: Levels and risks of depression and anxiety symptomatology among diabetic adults. Diabetes Care 1997; 20: 585-590.

19 Lloyd CE, Wing RR, Orchard TJ, Becker DJ: Psychosocial correlates of glycemic control: The Pittsburgh Epidemiology of Diabetes Complications (EDC) Study, Diabetes Res Clin Pract 1993; 21: 187-195.

20 Mühlhauser I: Verbesserung der Behandlungsqualität der chronischen Krankheiten Diabetes mellitus, arterielle Hypertonie und Asthma Bronchiale durch strukturierte

Therapie- und Schulungsprogramme. Med Habilitationsschrift, München, Wien, Baltimore, Urban Schwarzenberg, 1993.

21 Lustman PJ, Griffith SL, Clouse RE: Depression in adults with diabetes: Results of 5yr follow up study. Diabetes Care 1988; 11: 605-612.

22 Sachs G, Spiess K, Moser G, Prager R, Kunz A, Schernthaner G. Glykosyliertes Hämoglobin und Glukose - Selbstmonitoring (Compliance) bei depressiven und nicht depressiven Typ I-Diabetikern. Psychother Psychosom med Psychologie 1991; 41: 306-312.

23 Tewes U, Koschera A, Basler H-D, Brinkmann R, Brinkmeier U: Modifiaktion des Gesundheitsverhaltens von adipösen Patienten mit Typ-2-Diabetes, die nicht Insulin spritzen, in der allgemeinärztlichen Praxis. Zeitschr Med Psychol 1995; 3: 109-117.

24 Jacobson A, Barofsky I, Cleary P, Rand L: The DCCT Research Group: Reliability and validity of a diabetes Quality-of-Life measure for the diabetes control and complications trial (DCCT). Diabetes Care 1988; 11: 725-732.

25 Aaronson NK, Bullinger M, Ahmedzai S: A modular approach to quality-of-life assessment in cancer clinical trials. Recent Results in Cancer Research 1988, 11, 111: 231-249.

26 Bradley C, Lewis KS: Measures of psychological well being and treatment satisfaction developed from responses of people with tablet treated diabetes. Diabet Med 1990; 7:445-451.