EPIDEMIOLOGY/HEALTH SERVICES RESEARCH

The Association Between Patient-Reported Self-management Behavior, Intermediate Clinical Outcomes, and Mortality in Patients With Type 2 Diabetes: Results From the KORA-A Study

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OBJECTIVE

Little is known about the impact of diabetes self-management behavior (SMB) on long-term outcomes. We aimed to examine the association among patient-reported SMB, intermediate clinical outcomes, and mortality in patients with type 2 diabetes.

RESEARCH DESIGN AND METHODS

Data were collected from 340 patients with type 2 diabetes of the KORA-A study (1997/1998) who were recruited from two previous population-based surveys (n = 161) and a myocardial infarction registry (n = 179) in southern Germany. Based on previous methodological work, a high level of SMB was defined as being compliant with at least four of six different self-care dimensions, comprising physical exercise, foot care, blood glucose self-monitoring, weight monitoring, having a diet plan, and keeping a diabetes diary. The vital status of the participants was observed until 2009. Multivariable linear, logistic, and Cox regression models were applied to assess the association with intermediate clinical outcomes at baseline and to predict mortality over the follow-up period, adjusted for sociodemographic, behavioral, and disease-related factors.

RESULTS

In the cross-sectional perspective, a high level of SMB was weakly associated with a lower glycated hemoglobin A_{1c} level (−0.44% [−4.8 mmol/mol] [95% CI −0.88 to 0.00]), but not with low-density lipoprotein cholesterol, systolic blood pressure, or the presence of microalbuminuria, peripheral arterial disease, or polyneuropathy. During a mean follow-up time of 11.6 years, 189 patients died. SMB was a preventive factor for all-cause (hazard ratio 0.61 [95% CI 0.40–0.91]) and cardiovascular mortality (0.65 [95% CI 0.41–1.03]).

CONCLUSIONS

Although measuring SMB is difficult and the used operationalization might be limited, our results give some indication that a high level of SMB is associated with prolonged life expectancy in patients with type 2 diabetes and highlight the potential impact of the patients' active contribution on the long-term trajectory of the disease. We assume that the used proxy for SMB is associated with unmeasured, but important, dimensions of health behavior.

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Diabetes mellitus is a chronic metabolic disorder and major public health problem that is associated with an increased risk of microvascular and macrovascular complications, premature death, reduced quality of life, and significantly increased health care costs (1–3). Following the predictions of the International Diabetes Federation (4) regarding future diabetes incidence, the medical and economic burden of the disease will increase further, resulting in an urgent need for efficient preventive and curative strategies.

With the St. Vincent Declaration in 1989, for the first time European countries formulated strategic targets and action plans to improve the quality of diabetes care, to enhance patients' self-management, and ultimately to reduce diabetes-related complications (5). Reinforced by a vast body of research showing that intensive drug therapy, appropriate risk factor control, and screening for diabetes-related complications are cost-effective interventions to reduce the burden of diabetes, great efforts have been made to increase the quality of diabetes care (6–8). Although routine care often still falls short of reaching targeted goals, there is some evidence that the implementation of evidence-based treatment guidelines and structured disease management programs has improved the quality of care on a large-scale basis (9,10).

As the major part of day-to-day care is handled by the patients themselves, it is assumed that self-management behavior (SMB) is an important and modifiable element in the disease management process that is crucial in determining health outcomes (11,12). Reflected by the multidimensional practice of activities that patients initiate on their own to maintain health, self-management is seen as a context-dependent health resource depending on individual needs, goals, and priorities, as well as on medical recommendations (13,14). Previous cross-sectional studies predominantly identified factors that are associated with self-care activities, such as socioeconomic status, sex, and diabetes education, but rarely investigated associations between SMB and health outcomes (15–17). Results from randomized trials have shown that self-management education moderately improved self-care and SMB, as well as short-term glycemic control; however, the sustainability of these effects over time has not yet been studied (18,19). To the best of our knowledge, also only a few observational studies have analyzed the association between single dimensions of SMB, such as self-monitoring of blood glucose (SMBG) and mortality (20,21), but none has yet examined this relationship by accounting for the multidimensional character of patient SMB. The lack of studies targeting this important research question might be related to the fact that despite methodological efforts in the development of approaches to assess self-management, measuring this highly individualized and complex construct has proved to be difficult. Therefore, current instruments often focus on specific self-care activities and behaviors, such as blood glucose self-monitoring, foot care, or physical activity, that are assumed to be universally important for all patients with diabetes (15,16,22–24). One approach to define SMB has been proposed by Arnold-Wörner et al. (15), who tested a multidimensional compliance index in a population-based sample of patients with type 2 diabetes.

The objectives of this study are, first, to analyze the cross-sectional association between diabetes SMB and intermediate clinical health outcomes at baseline, and, second, to examine the predictive value of SMB on mortality by linking the self-management index of Arnold-Wörner et al. (15) with data from a 12-year mortality follow-up.

RESEARCH DESIGN AND METHODS

Data Source

The data were taken from the population-based KORA-A study (Cooperative Health Research in the Region of Augsburg). For the KORA-A study (1997/1998, n = 1,002), all subjects from two previous population-based MONICA/KORA surveys (S2, S3) and from the MONICA/KORA Myocardial Infarction Registry with a physician-validated diagnosis of diabetes were invited, together with sex- and age-stratified nondiabetes matches. The MONICA/KORA surveys S2 (1989/1990, participation rate 76.9%) and S3 (1994/1995, participation rate 74.9%) were part of the multinational World Health Organization MONICA project and included 4,940 and 4,856 noninstitutionalized inhabitants, respectively, aged 25–74 years living in the city of Augsburg and two surrounding counties in southern Germany. In the MONICA/KORA Myocardial Infarction Registry, all hospitalized cases of acute myocardial infarction (MI) among subjects aged 25–74 years from the same study area have been registered since 1985. The study design, sampling methods, and measurement procedures of the KORA/MONICA studies and the registry have been described in detail elsewhere (25,26). The KORA-A survey was conducted in 1997/1998, and included a standardized interview assessing socioeconomic characteristics, risk factors, and medical history; a comprehensive questionnaire incorporating questions about received diabetes care and self-care behavior; an assessment of medication; and a physical examination including blood and urine samples. The participation rate of subjects with diabetes was 61.7% for those from the surveys and 71.4% for those from the Myocardial Infarction Registry. The survival status of all subjects was observed until 2009. All participants gave written informed consent, and the study was granted full ethical approval by the ethics commission of the Bavarian Medical Association.

Measures

SMB at Baseline

SMB was defined by a multidimensional "compliance index," which was developed and tested in a previous study (15) on the same sample of patients using self-reported information from the interview and questionnaire. This compliance index comprises the following six different dimensions: performing regular physical exercise (at least 60 min/week), conducting regular foot care (checking for wounds at least once per week), SMBG (at least once a day for patients treated with insulin and at least twice a week for others), monitoring of body weight (at least once a week) in the last 6 months prior to examination, as well as currently keeping a diabetes diary and having a diet plan. According to this index, having a high level of SMB is defined as being compliant, that is, achieving the level of action in the referred time period with at least four out of six dimensions. The development and the properties of this index have been described in detail elsewhere (15).

Intermediate Clinical Outcomes at Baseline

Parallel to the collection of data about SMB, established screening tests were performed to detect microalbuminuria, defined by a urine albumin-to-creatinine ratio of ≥30 mg/g (albumin: immunoturbidimetric test, Tina-quant; creatinine: enzymatic colorimetric test, Boehringer Mannheim); polyneuropathy, defined by a Michigan Neuropathy Screening Instrument score of >2; as well as peripheral arterial disease (PAD), defined by an ankle–brachial index of <0.9 (Mini Dopplex device; HNE Huntleigh Nesbit Evans Healthcare).

Also, glycated hemoglobin A_{1c} (HbA_{1c}; immunologic test kit, Tina-quant; Boehringer Mannheim) and LDL (enzymatic method, cholesterol oxidase/p-aminophenazone, Boehringer Mannheim) concentrations were obtained from nonfasting venous blood samples, and systolic blood pressure was assessed as the average of the second and third of three measurements obtained from patients while in a sitting position (random zero sphygmomanometer; Hawksley & Sons Ltd.).

Mortality Over the Follow-up Period

The vitality status of all participants was assessed in a mortality follow-up conducted between October 2008 and December 2009. Information was obtained by address search and by contacting the regional registration authorities. There were only 26 participants with a shorter follow-up time. The mean follow-up time until censoring was 11.6 years. The underlying cause of death was obtained from death certificates and was classified into all-cause mortality (ICD-9 code 001–999) and cardiovascular disease (CVD) mortality (ICD-9 codes 390–459, 798).

Covariates Assessed at Baseline

Sociodemographic characteristics, including sex, age (in years), and education (primary education, ≤9 years of school; secondary/tertiary education, >9 years of school); as well as information about treatment regimen (diet and lifestyle only, oral antidiabetic drugs, insulin); diabetes duration (in years); smoking status (smoker/ex-smoker vs. never-smoker); objectively assessed weight status (normal weight, BMI <25 kg/m^2; overweight, BMI ≥25 and <30 kg/m^2; obesity, BMI ≥30 kg/m^2); and self-reported history of MI, stroke, retinopathy, neuropathy, and nephropathy (kidney insufficiency or dialyses) were retrieved from the interview, the questionnaire, and the physical examinations.

To assess medication, patients were asked to bring the original packaging of the pharmaceutical products taken during the last 7 days prior to the examination. Based on this information, Anatomical Therapeutic Chemical Classification System codes were assigned to define the use of antihypertensive medication (C02–C04 and C07–C09), lipid-lowering medication (C10), and aspirin and nonaspirin antiplatelet medication (B01AC06 and N02BA01, and B01AC and B01AB).

Statistical Analysis

Descriptive statistics of the baseline characteristics are reported for the entire sample and also separately for patients with high and low levels of diabetes SMB. Differences in the characteristics between these two groups were tested by ANOVA for continuous variables, and by χ^2 tests for categorical variables.

To analyze the cross-sectional association between diabetes self-management and intermediate clinical outcomes at baseline, logistic regression models were applied for binary outcomes and ordinary least-squares regression models for continuous outcomes. These models were adjusted for a basic set of covariates including sociodemographic variables, severity of diabetes, history of disease, and, in a second step, also for medication.

Using the same sets of covariates, multivariate Cox proportional hazards regression was applied to predict all-cause mortality and CVD mortality over the follow-up period according to the baseline level of SMB. The proportional hazards assumption was tested using the Kolmogorov-type supremum test. In each model, covariates violating the proportional hazards assumption were introduced as time-covariate interactions. To detect possible effect modifiers in the survival models, all two-way interactions between the basic set of covariates and the self-management variable were tested. Except for education, none was significant at a 5% level. Accordingly, Cox models were finalized without interaction terms, but separate models were calculated for subpopulations with high or low levels of education. In a final step, models were also adjusted for intermediate clinical outcomes (microalbuminuria, polyneuropathy, PAD, HbA_{1c}, LDL cholesterol, and systolic blood pressure).

To account for the great importance of CVD comorbidity among diabetes patients and to avoid potential bias related to the methodological property of the self-management index, in which the threshold for blood glucose self-monitoring depends on the treatment status, all models were in addition stratified for CVD comorbidity (previous MI or stroke vs. no CVD event) and treatment status (insulin-treated vs. not insulin-treated).

In order to avoid power reduction related to the multivariate adjustment of models, we applied a Markov chain Monte Carlo method to impute missing covariates. We performed single instead of multiple imputations because of the relatively low percentage of missing values and the high computational effort associated with analyzing models based on multiple imputed data sets. To assess the sensitivity of the results to missing data, we refitted a random sample of the models with a multiple imputation approach. Further, we performed detailed analyses for each of the six self-management dimensions and applied Cox regression models using the cumulative number of compliant dimensions instead of the predefined dichotomized self-management index.

RESULTS

Characteristics of the Study Population

From the 397 participants who answered the diabetes questionnaire, 367 were identified as having type 2 diabetes (surveys, n = 172; Myocardial Infarction Registry, n = 195). According to the self-management index, 66 of these study subjects reported having a high level of SMB (≥4 compliant self-management dimensions), whereas 274 subjects were categorized as having a low level of SMB. Because of missing values, no categorization was possible for 27 study subjects. The characteristics of the sample at baseline (1997/1998, n = 340) according to level of diabetes self-management are shown in Table 1. The mean age was 67.2 years. Some 70% of the study subjects

Table 1—Sample characteristics at baseline (1997/1998) stratified by the level of SMB

			Self-management index				
Variables	All (N = 340)		High level of SMB (n = 66)		Low level of SMB (n = 274)		P value
Age, mean (SD), years	67.2	(8.2)	65.1	(8.3)	67.7	(8.1)	0.017*
Diabetes duration, mean (SD), years	13.5	(9.5)	14.7	(8.8)	13.3	(9.7)	0.257*
Sex							0.856†
Men	239	(70.3)	47	(71.2)	192	(70.1)	
Women	101	(29.7)	19	(28.8)	82	(29.9)	
Education							0.180†
Primary	253	(74.6)	45	(68.2)	208	(76.2)	
Secondary	86	(25.4)	21	31.8	65	23.8	
Treatment							0.063†
Diet	47	(13.8)	4	(6.1)	42	(15.4)	
Oral medication	175	(51.5)	33	(50.0)	141	(51.8)	
Insulin	118	(34.7)	29	(43.9)	89	(32.7)	
Weight status							0.764†
Normal weight	35	(10.8)	7	(11.3)	28	(10.7)	
Overweight	154	(47.7)	27	(43.6)	127	(48.7)	
Obese	134	(41.5)	28	(45.2)	106	(40.6)	
Smoker (vs. never smoker)	205	(60.3)	41	(62.1)	163	(59.9)	0.735†
Macrovascular events							
MI	195	(57.4)	40	(60.6)	153	(56.3)	0.552†
Stroke	33	(9.7)	7	(10.6)	26	(9.6)	0.783†
Microvascular complications							
Nephropathy	9	(3.3)	0	(0)	9	(4.1)	0.216‡
Retinopathy	55	(19.5)	13	(24.5)	42	(18.4)	0.306†
Neuropathy	41	(12.2)	12	(18.5)	29	(10.8)	0.088†
Medication							
Antihypertensive agents	255	(75.0)	48	(72.7)	207	(75.6)	0.635†
Lipid-lowering agents	67	(19.7)	13	(19.7)	54	(19.7)	0.998†
Antiplatelet agents	196	(57.7)	39	(59.1)	156	(56.9)	0.791†
Compliant dimensions of self-management index							
Exercising	85	(25.0)	32	(48.5)	53	(19.3)	<0.001†
Foot care	156	(46.6)	58	(89.2)	98	(36.3)	<0.001†
SMBG	95	(27.9)	48	(72.7)	47	(17.2)	<0.001†
Weight monitoring	204	(60.4)	64	(98.5)	140	(51.3)	<0.001†
Diet plan	127	(39.1)	43	(68.3)	84	(32.1)	<0.001†
Diabetes diary	85	(26.1)	43	(67.2)	42	(16.0)	<0.001†

Values are given as n (%), unless otherwise stated. *ANOVA. †χ^2 test. ‡Fisher exact test.

were male, 89% were either overweight or obese, and approximately one-third of subjects reported insulin intake. In total, 60% of the participants already had experienced a cardiovascular event (MI or stroke).

Cross-sectional Association Between SMB and Intermediate Clinical Outcomes

The adjusted odds ratios (ORs) of a positive screening for microalbuminuria (prevalence 48%), polyneuropathy (prevalence 33%), and PAD (prevalence 20%) according to the level of self-management are depicted in Table 2. In general, the likelihood of these outcomes was slightly lower for patients with a high level of SMB compared with those with a low level of SMB (ORs between 0.65 and 0.88); however, none of the revealed associations was statistically significant.

Table 2 further shows the adjusted mean differences concerning HbA_{1c} (mean 7.1%), LDL cholesterol (134 mg/dL), and systolic blood pressure (143 mmHg) from multivariate ordinary least-squares regression models. Study subjects with a high level of SMB had a borderline significantly better HbA_{1c} value (mean difference −0.44% [−4.8 mmol/mol] [95% CI −0.88 to 0.00]) than their less compliant counterparts. LDL cholesterol and systolic blood pressure levels did not differ significantly between patients with good or poor self-management. The additional adjustment for medication (see model 3) had hardly any effect in both the logistic and the linear regression models.

Association Between SMB and Mortality

In total, 189 of the 340 patients (56%) died, 148 (44%) from CVD. The adjusted hazard ratios (HRs) for all-cause and CVD mortality are illustrated in Table 3.

All-Cause Mortality

Controlling for a basic set of covariates, diabetes patients with high level of SMB had a 39% reduced risk of dying (HR 0.61 [95% CI 0.40–0.91]). This effect appeared to be robust after controlling for antihypertensive, lipid-lowering,

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Table 2—Cross-sectional association between the level of SMB and intermediate clinical outcomes

Variables	Model	Diabetes complications from multivariate logistic regression, adjusted OR (95% CI)			Clinical parameters from multivariate ordinary least-squares regression, adjusted mean difference (95% CI)		
		Microalbuminuria	Polyneuropathy	PAD	HbA_{1c}, % [mmol/mol]	LDL cholesterol, mg/dL	Systolic blood pressure, mmHg
Prevalence		47.8%	33.2%	20.3%			
Mean					7.1 [54]	134.2	143.3
High vs. low level of SMB							
All patients	1	0.71 (0.40–1.27)	0.88 (0.47–1.65)	0.65 (0.30–1.42)	−0.44 [−4.8] (−0.88 to 0.00)	5.1 (−5.9 to 16.1)	−2.3 (−8.0 to 3.4)
	2	0.73 (0.41–1.32)	0.79 (0.41–1.53)	0.65 (0.30–1.42)	−0.43 [−4.7] (−0.88 to 0.01)	5.3 (−5.7 to 16.4)	−1.9 (−7.5 to 3.7)
	3	0.74 (0.41–1.33)	0.74 (0.38–1.46)	0.68 (0.31–1.52)	−0.45* [−4.9] (−0.90 to −0.01)	5.8 (−5.2 to 16.8)	−1.8 (−7.4 to 3.8)
Stratified models							
CVD†	2	0.62 (0.29–1.34)	0.72 (0.32–1.62)	0.68 (0.27–1.68)	−0.22 [−2.4] (−0.73 to 0.29)	−0.6 (−15.1 to 13.9)	−3.4 (−9.8 to 3.0)
No CVD	2	‡	‡	‡	−0.92* [−10.1] (−1.81 to −0.02)	15.6 (−2.7 to 33.9)	−1.9 (−12.8 to 9.0)
Insulin-treated	2	‡	0.36 (0.12–1.07)	0.49 (0.16–1.50)	−0.36 [−3.9] (−1.05 to 0.32)	8.2 (−10.1 to 26.5)	−1.8 (−10.3 to 6.7)
Not insulin-treated	2	0.63 (0.28–1.40)	‡	‡	−0.32 [−3.5] (−0.92 to 0.28)	4.9 (−9.6 to 19.5)	−0.3 (−7.5 to 6.9)

Model 1, adjusted for age, sex, education, smoking status, BMI, diabetes treatment, diabetes duration; Model 2, adjusted for Model 1 plus history of CVD, neuropathy, nephropathy, retinopathy; Model 3, adjusted for Model 2 plus medication (antihypertensive, lipid-lowering, and antiplatelet agents). *$P < 0.05$. †Patients with previous MI or stroke. ‡No estimate (maximum likelihood criterion not satisfied).

and antiplatelet medication in model 2, as well as after additional adjustment for intermediate clinical outcomes in model 3 (0.62 [0.41–0.94]).

CVD Mortality

Similar but nonsignificant effects were observed for CVD mortality. A high level of self-management was associated with a 35% reduced hazard of dying from any CVD cause (HR 0.65 [95% CI 0.41–1.03]). The risk reduction was slightly smaller after also adjusting for intermediate clinical outcomes in model 3 (0.71 [0.44–1.13]).

Other determinants with a significant predictive value ($P < 0.05$) for all-cause mortality in the extended Cox model (model 3) were CVD (HR 2.70), insulin medication (HR 2.21), age (HR_{year} 1.09), self-reported retinopathy (HR 1.88), and detected microalbuminuria (HR 1.94).

Modifying Effect of Education

A significant interaction effect with SMB was found for education ($P < 0.01$ for all-cause-mortality). Among study participants with a low level of education (≤9 years of school), a high level of SMB was associated with a reduced all-cause mortality (HR 0.44 [95% CI 0.26–0.74]), but an opposite picture was seen among participants with a high level of education (>9 years of school); that is, a high level self-management was associated with an increased but nonsignificant risk of all-cause mortality (1.68 [0.76–3.69]).

Figure 1 graphically displays the raw Kaplan-Meier survival curves by the level of self-management for the entire sample (log-rank test, $P = 0.04$), as well as for patients with CVD comorbidity ($P = 0.02$), for insulin-treated patients ($P = 0.05$), and for patients with a low level of education ($P = 0.02$).

Sensitivity Analysis

To identify the dimensions of the self-management index that mainly contributed to the observed effects, we performed separate Cox regression models for each of the six dimensions, using the basic set of covariates. Being compliant with the dimensions "exercising" (HR 0.84 [95% CI 0.60–1.19]), "foot care" (0.85 [0.63–1.14]), "body weight monitoring" (0.76 [0.54–1.06]), "self-monitoring of blood glucose" (0.84 [0.62–1.14]), and "having a diabetes diary" (0.80 [0.56–1.15]) was associated with a reduced but

Table 3—HRs for all-cause and CVD mortality of multivariate Cox proportional hazards regression according to the level of diabetes SMB

High vs. low (reference) level of SMB	Model	All-cause mortality (n = 189) HR (95% CI)	All-cause mortality (n = 189) P value	CVD mortality (n = 148) HR (95% CI)	CVD mortality (n = 148) P value
All patients	1	0.61* (0.40–0.91)	0.016	0.65 (0.41–1.03)	0.064
	2	0.60* (0.40–0.90)	0.013	0.64 (0.41–1.02)	0.061
	3	0.62* (0.41–0.94)	0.026	0.71 (0.44–1.13)	0.145
Stratified models					
CVD†	1	0.59* (0.37–0.95)	0.031	0.63 (0.38–1.04)	0.068
No CVD	1	0.66 (0.27–1.64)	0.372	0.79 (0.22–2.87)	0.721
Insulin-treated	1	0.57 (0.31–1.07)	0.080	0.53 (0.26–1.12)	0.096
Not insulin-treated	1	0.66 (0.38–1.15)	0.143	0.79 (0.44–1.43)	0.437

Model 1, adjusted for age, sex, education, smoking status, weight status, diabetes treatment, diabetes duration, history of CVD, retinopathy, neuropathy, nephropathy; Model 2, adjusted for Model 1 plus medication (antihypertensive, lipid-lowering, and antiplatelet agents); Model 3, adjusted for Model 2 plus intermediate clinical outcomes (microalbuminuria, polyneuropathy, PAD, HbA_{1c}, LDL cholesterol, and systolic blood pressure). *$P < 0.05$. †Patients with previous MI or stroke.

nonsignificant mortality risk, whereas the dimension "having a diet plan" (1.20 [0.88–1.63]) was associated with a nonsignificant elevated mortality risk. Using the cumulative number of compliant dimensions as a linear predictor in the Cox models showed a borderline significant mortality risk reduction of 8–12% for every additional compliant dimension. Applying a multiple imputation method for missing covariates yielded similar HRs and CIs to the single imputation approach.

CONCLUSIONS

Patient self-management is assumed to be an important factor for the successful management of diabetes. To the best of our knowledge, this study is the first to analyze the relationships among a multidimensional measure of SMB, intermediate outcomes, and mortality. A high level of patient SMB was associated with improved glycemic control in the cross-sectional perspective and prolonged life expectancy over a follow-up period of 12 years.

With a 40% mortality risk reduction, the predictive value of the multidimensional self-management index was almost as strong as that seen for clinical parameters, such as microalbuminuria or retinopathy, and was considerably greater than those of single self-management dimensions. This finding indicates that different dimensions of self-management are important for patients to manage the disease and highlights the importance of capturing the complex structure of SMB in future research. Despite the plausibility of increased life expectancy through better risk factor tracking (diabetes diary, weight monitoring), earlier detection of diabetes complications (foot care), or better glycemic control and fitness (SMBG, exercising), we actually think that the effect shown here cannot be attributed solely to the six dimensions included in the self-management index. We rather assume that the index reflects general multilayered SMB, including behavior that we can hardly assess in its full complexity. Patients who measure and track their blood glucose level and risk profile regularly might, for example, be more likely to have better physician attendance and medication adherence, and those habitually monitoring their weight, feet, and blood glucose level may in general be more attuned and sensitive to their body, possibly resulting in avoidance, earlier detection, or better coping with adverse clinical conditions, such as extreme hyperosmolar periods, hypoglycemia, or (silent) cardiovascular events.

Because of its multidimensionality, the accurate assessment of SMB is difficult (27). Numerous questionnaires and scales based on different theoretical frameworks have been developed in the past (15,16,22,24), and were accompanied by controversial discussions about the rather passive concept of compliance and the more proactive concepts of adherence, self-care, and self-management (28–30). The approach of assessing and defining SMB in this study also has some limitations. First, the SMB index that was used does not include other important dimensions such as medication adherence or interaction with health care professionals. Second, the methodological approach of summarizing quite heterogeneous dimensions of SMB in a global index might be debatable. Third, one could argue that the index is a rather pragmatic approach that cannot be clearly assigned to one of the mentioned theoretical concepts. However, this index was already tested on this sample of patients, contains similar dimensions of proactive patient behavior as the well-established Summary of Diabetes Self-Care Activities scale, and has been shown to include dimensions that do not correlate highly with each other, a property that was also found for self-care activity items in other instruments (23). From our perspective, this index can therefore be considered as a limited, but satisfactorily valid, proxy for the multidimensional SMB of patients with diabetes.

Furthermore, our results are predominantly consistent with findings from the few studies on this topic. A positive cross-sectional association between self-management measured by the Summary of Diabetes Self-Care Activities scale and HbA_{1c} was reported by Osborn et al. (31). There is also some growing evidence from randomized studies that self-care behavior itself as well as glycemic control can be positively influenced by active self-management training and diabetes education (18,19). Despite a lack of evidence from randomized studies for the effect of SMB on long-term outcomes, there is some weak indication that specific dimensions of SMB are associated with prolonged life expectancy among diabetes patients. A recent meta-analysis (32) showed that 1-MET/h/day incrementally higher physical activity was associated with a 9.5% reduction in all-cause mortality. Based on data from the multicenter ROSSO (Retrolective Study Self-Monitoring of Blood Glucose and Outcome) study, Martin et al. (20) reported in their debatable study that SMBG reduces the mortality risk by 50% (33); however, in contrast no effect on all-cause mortality was found in the observational prospective Fremantle Diabetes Study (21). Another large study

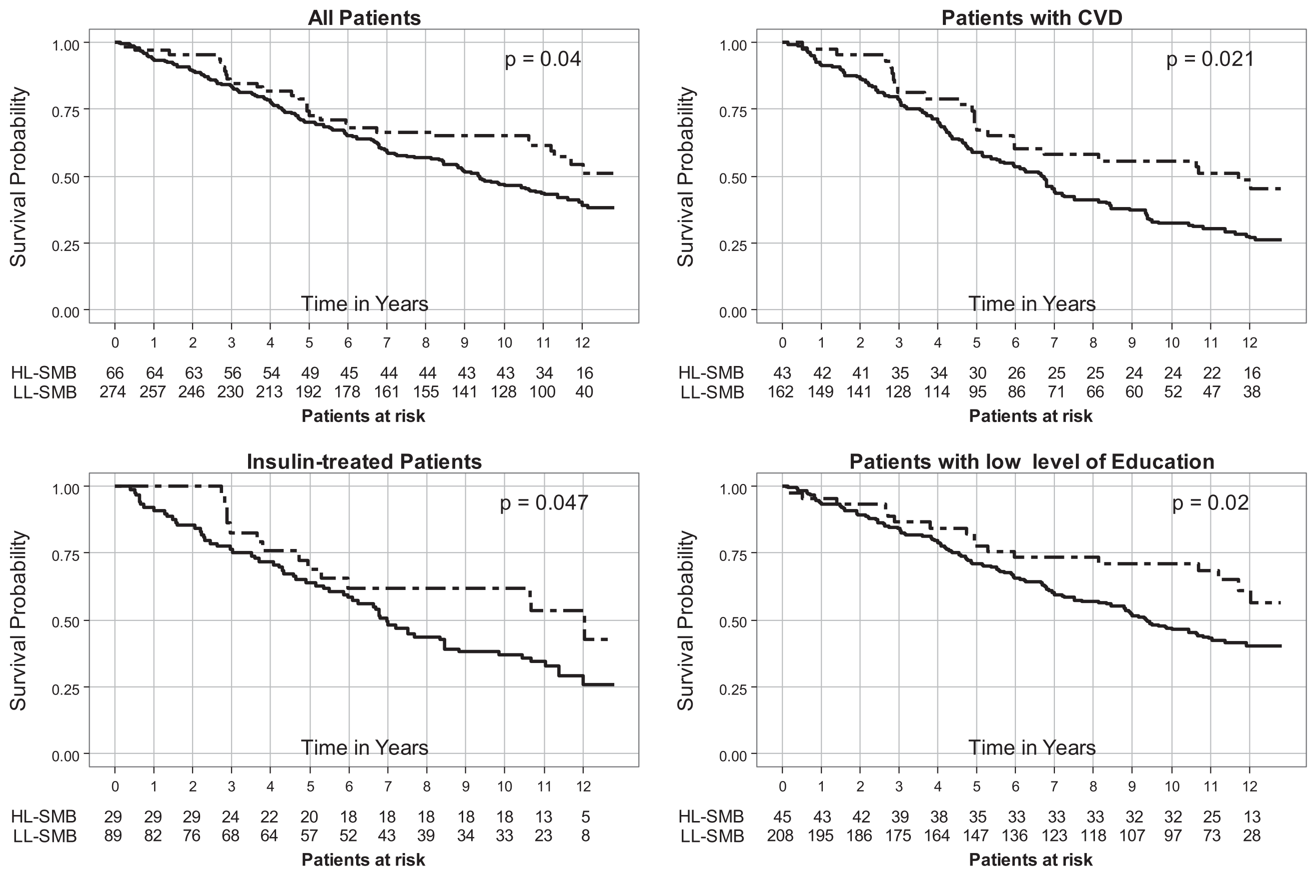

Figure 1—Kaplan-Meier survival curves according to the level of SMB. High level of SMB (HL-SMB; dashed line) and low level of SMB (LL-SMB; solid line). *P* value was determined by log-rank test.

based on U.K. general practice records showed that medication nonadherence and clinic appointment nonattendance, two dimensions that may also play an important role in diabetes self-management, are associated with 58% and 16–61%, respectively, increased all-cause mortality (34). Even though the predictor variables in these studies were different and not multidimensional, it is possible that the observed reductions in mortality were rather attributable to other, unmeasured, components of self-management associated with the tested predictors.

Arnold-Wörner et al. (15) reported in their study a positive association among SMB, participation in diabetes education, and treatment satisfaction. However, further analyses of our data showed that these latter two factors, as well as general diabetes knowledge, were not predictive for mortality (results not shown). This indicates that SMB, diabetes education, quality of care, and self-management knowledge are mutually dependent factors in the management of diabetes, but that the actual behavior of patients seems to be most predictive for long-term health outcomes.

Our study further shows that the general level of education might play an important role in the context of the patients' health behavior and health outcomes. The data indicate that patients with a low level of education benefit from good SMB, leading to reduced mortality, whereas patients with a high level of education do not profit from it. Although education is assumed to be important to transform knowledge into health behavior and health outcomes, the great positive effect of SMB among less educated patients seems to be plausible, because poorly educated patients might gain greater benefits from basic health education and its application than already highly educated and generally well-performing counterparts (35).

The results of this study highlight the potential benefit of proper SMB on patient health. From a translational perspective, effective and cost-effective programs that are at the same time comprehensively implementable and also able to reach patients with a low level of education would, therefore, be highly recommended to improve patient SMB and, potentially, health outcomes. As studies showed that peer support led by clinical staff, peer coaches, or community health workers can be an effective low-cost method to improve SMB, the implementation of comprehensive peer networks seems to be a promising extension to classical structured diabetes education and care management interventions, which are rather labor- and cost-intensive (36,37). In addition to the classic face-to-face peer group support, the potential of innovative telephone/self-management support or e-mail/web-based support techniques also need to be considered (37). Further, most importantly, strategies proven to be effective, cost-effective, and feasible to implement should be rapidly adapted by health care providers, even though adaptations will require changes in the current system of care and remuneration schemes. In addition, from a scientific perspective, the collection of data about physician-delivered diabetes education and patient-reported SMB should, where possible, be routinely assessed and incorporated into electronic health records, as such data sources are necessary to enhance population-based health services research and to strengthen the patient-centered perspective in health care (38,39).

The strengths of this study are the selection of participants from two population-based samples originating from the same study area and the long follow-up time. Linking a predefined self-management index that had already been tested in the same sample of patients with a 12-year mortality follow-up gave us an exceptional data source to analyze the association among SMB, objectively assessed clinical outcomes, and mortality with a clear a priori hypothesis, while at the same time adjusting for medical history, medication intake, treatment regimen, sociodemographic factors, and clinical parameters. Further, the analytic approach of examining both the cross-sectional association with intermediate outcomes, as well as the longitudinal association with mortality enabled us to gain a better understanding of potential underlying mechanisms in the observed relationships.

Our study also had a few limitations that need to be discussed. Despite the fact that a high internal consistency was reported in other KORA studies for different items of treatment adherence and diabetes knowledge, the validity and reliability of self-reports in our study remain unknown. In addition, we only had information about the level of self-management at one point in time and do not know the intraindividual stability of patient behavior over time, which is one of the key assumptions for the plausibility of the observed associations. However, we assume that this limitation is rather likely to have introduced nondifferential bias, resulting in an underestimation of the observed effects. Another weakness of the study is its observational design. Even though we controlled for most of the variables that are known to impact mortality among diabetes patients, we cannot rule out the possibility of residual confounding, nor can we clearly state the direction of the observed associations specifically in the cross-sectional perspective (40). Unmeasured dimensions like patient expectations, self-efficacy, general quality of care, and socioeconomic status possibly interacted with self-management and life expectancy. And particular aspects of mental health, such as depression, which are known to be predictive for mortality and are generally associated with health behavior, might have biased effect estimates. It also has to be emphasized that the number of participants was limited and that incomplete data on covariates had to be imputed to avoid a further reduction in power. Whereas our sensitivity analyses indicated that the latter point is rather unproblematic, the relatively small sample size prohibited a more detailed and stratified analysis of the data and restricted the power of our models. Finally, the sampling of participants from two different population-based data sources yielded an over-representation of men with previous myocardial events, which limits the external validity and generalizability of our results.

Despite its limitations, this study indicates that a high level of self-management is associated with prolonged life expectancy. Further refinement of current self-management measures and the inclusion of these instruments in long-term observational studies, routinely assessed health care records, and randomized controlled trials are necessary to improve the understanding of patients' active role in disease management and to derive practical implications for future directions in diabetes self-management education.

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