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Results from the population-based KORA survey in Germany

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1. Abstract

Aims: Health-related changes in leisure time are supposed to be implicitly considered by participants of health state valuations. The amount of empirical research on whether respondents in fact include the effects of morbidity on leisure into health state valuations is limited and the results are inconclusive. In this exploratory study, we analyze whether time aspects of diabetes self-care might explain the ratings of the health state (HSR) in addition to the effects of physical and mental health-related quality of life.

Methods: Using the data from participants with diagnosed type 2 diabetes in the population-based KORA FF4 study (n=190, 60% Male, mean age 69±10 years), multiple logistic regression models were fitted to explain HSR (good vs. poor) in terms of the SF12 physical and mental component scores, time spent on diabetes self-care and a range of background variables. We assume that if time spent on diabetes self-care competes with other leisure activities and implicitly plays a role in HSR, this additional effect should be seen in regression models.

Results: There was no significant association between time spent on diabetes self-care and HSR in models without interaction. Significant interaction term was found between physical score of SF12 and time spent on self-care. In models with interaction self-care time has a small, but significant impact on the HSR. In particular, for a fixed physical score of SF12 value under 40, more time increases the chance to rate the health state as "good", while for physical score value above 40 there is a reverse effect.

Conclusions: The additional impact of self-care time on HSR in our sample is small and more complex than a simple linear association. More research is needed on whether inclusion of health-related leisure time changes in the denominator of cost-effectiveness analysis is sufficient.

Key words: patient time use; diabetes mellitus; health economic evaluation, population-based study

2. Introduction

Time spent engaging in healthy behaviors and self-care is a resource that is essential for maintaining or improving health. Time spent on health-related activities has to be considered particularly in chronic diseases as e.g. diabetes mellitus. Diabetes mellitus affects more than 400 million people worldwide [1]. Diabetes management relies largely on activities carried out by patients, such as glucose self-testing, insulin injections, foot care, dietary changes and exercise. Available studies of diabetes self-management show that patient time costs can be substantial – sometimes larger than direct medical costs of an an intervention [2, 3]. Professional diabetes educators estimated that, people in a stable phase of diabetes care require over 2 hours per day to complete self-care tasks recommended by the American Diabetes Association [2]. In a population-based study in people with diabetes, mean time for diabetes self-management was estimated to be 149 minutes (119-181) per person and week, accounting to 129 (103-157) hours per person and year. The largest proportion of time spent on self-management was due to lifestyle activities such as dietary changes and exercise [3], which will probably compete with other leisure time activities and may affect quality of life as well as willingness to engage in and adhere to self-care behavior.

Considering increasing expenditures needed for health care systems, economic evaluations has become more important in order to inform decision makers whether current and new technologies are efficient. Often, costs and effects of health care interventions are compared using cost–utility analysis (CUA), that means the evaluation of additional cost per quality-adjusted life-years (QALYs) gained. One of ongoing methodological debates in the context of economic evaluation is related to the incorporation of different elements of health-related patient time use into the analysis [4-12]. The US Panel on Cost-Effectiveness in Health and Medicine recommended that patient time spent in seeking care and treatment should be included as a cost, i. e. in the numerator of the cost-effectiveness (CE) ratio [4]. The Panel also recommended that health-related changes in time spent on paid or unpaid work and leisure should be included in the denominator of the CE ratio because they are implicitly considered by respondents of health state valuations. Thus for "the reference case analysis, health-

related quality of life should be captured by an instrument that, at minimum, implicitly incorporates the effects of morbidity on productivity and leisure".

Unlike the controversy regarding productivity costs, there is a broad consensus that leisure effects of ill-health *should be* included in the denominator of the CE ratio [4, 11, 12]. However, the amount of empirical research on whether respondents in fact include health-related leisure time changes into health state valuations is limited and the results are inconclusive [13-16]. Therefore, more knowledge on what respondents include in health state valuations and how this affects the subsequent results is required.

In this exploratory study, we have considered the ways in which time spent on diabetes self- care might explain the ratings of the health state in addition to the effects of physical and mental health-related quality of life assessed by the SF12 questionnaire. It is important to note that direct (positive) impact of self-care on the physical and mental ability to perform everyday activities and enjoy leisure time is probably captured by the SF12 questionnaire and we were interested specifically in investigating the influence of the time aspect of diabetes self-care on health state ratings.

3. Participants and Methods

3.1 Study design and population

Study design and population have been described in detail elsewhere [17]. Briefly, our cross-sectional study was performed within the KORA FF4 study, the second follow-up of the KORA S4 study (KORA: Cooperative Health Research in the Augsburg Region). The S4 study is a population-based health survey conducted in the city of Augsburg and two neighbouring counties between 1999 and 2001. A total sample of 6,640 subjects was drawn from the target population which included all German residents of the region aged 25 to 74 years [18]. Of the 4,261 participants in the S4 baseline study (64% response), 3,319 persons were eligible for the 14-year follow-up FF4 study conducted from June 2013 to September 2014, and 2,279 participated (follow-up response rate of 68.7%). All participants received a comprehensive standardised clinical investigation, interviews and questionnaires [18].

When visiting the KORA study centre, participants were asked if they had a diabetes diagnosis or received glucose-lowering medication and, if so, which type of diabetes they had. If there was a diabetes indication (self-report, oral antidiabetic medication) their general practitioners (GPs) were contacted to validate the diagnosis and diabetes type [18]. Of the 2,279 participants, 227 (10.0%) were identified as having diagnosed type 2 diabetes. These participants were asked to complete the questionnaire to assess diabetes self-care time as described below, as well as the SF12 questionnaire which assesses health-related quality of life. 192 participants who had no missings in the SF12 questionnaire and less than or equal to 3 missings in self-care time questionnaire were included in our analyses (details regarding missings see below). We excluded two outliers in patient time (1365 and 1520 minutes per week) so that 190 participants were included in the final analysis.

3.2 Concept of the analysis

We use regression analyses to explain health state ratings in terms of the SF12 physical and mental component scores, time spent on diabetes self-care and a range of background variables. We assume that if time spent on diabetes self-care implicitly plays an important role in health state valuations, we should see this additional effect in regression models.

3.3 Instruments and variables

The main variables for our analysis were self-reported rating of health state in general, physical and mental health-related quality of life and time spent on diabetes self-care activities. Further variables were included to describe the population and explore possible confounders.

3.4 Statistical analysis

Descriptive analyses

Descriptive statistics are provided as frequencies and percentages or mean values, standard deviations, medians and interquartile ranges (IQR) depending on the nature of considered variables.

Missings in time variables

Six persons had one missing in answers to the 14 questions whether they spent time on particular diabetes-related activities, and one person three missings in these answers. In these cases, missings were set to '0' (no time) in our analysis. 23 persons had in total 44 missings in time variables related to particular self-care activities although they answered the corresponding question with "yes". In our main analysis we set all individual missing time variables to zero, while in the sensitivity analysis we imputed the corresponding medians of non-missing values. We believe that missings in time variables occurred rather for smaller values (i.e. missings not at random) so that our two approaches may represent two extreme scenarios, which narrowed the true data.

Regression analyses

Regression models were fitted to evaluate the impact of time spent on self-care on the rating of the general health status beyond the physical and the mental score of the SF12. We modelled the dichotomized version ("Excellent/Very good/Good: good", "Fair/Poor: poor") of the general health state ratings using multiple logistic regression with the following independent variables: the physical and mental component scores of the SF12 and time spent on self-care, cf. model (i) in Table 2. To study the impact of potential confounders we considered further multiple logistic regressions with additional independent variables: age and sex (cf., model (ii) in Table 2) and age, sex, school education (high/middle, low), employment status, partner, cf. model (iii) in Table 2.

4. Results

The sample (n=190) is described in detail in Table 1. The mean age was about 70 years, 60% of the sample were men. Two thirds of participants had low school education. 23% of participants were employed.

Median physical score of SF12 was 44.5 and median mental score of SF12 was 54.3. Almost 4 out of 5 participants rated their general health state as excellent or (very) good. Mean time spent on self-management activities was about 2 hours per week.

Table 2 displays the result of multiple logistic regressions. The estimated Odds Ratio (OR) to rate the general health status as "good" was 1.23 (95%-CI 1.15-1.32) when physical score of SF12 increases in one point and 1.14 (95%-CI 1.08-1.20) when mental score of SF12 increases in one point, cf. model (i). Both associations were highly significant (p-value <0.0001). However, there was no significant association between time spent on self-care and the rating of the general health status (OR=1.003, p-value 0.0692) within this model. Models (ii) and (iii) indicate that none of considered factors like age, sex, employment status, partner or school education changed the association between time spent on self-care and the rating of the general health state. The same results were obtained in the sensitivity analysis (data not shown).

To detect possible interactions between the physical and mental scores of SF12 and time spent on self-care, we performed backword selection that led to the significant interaction term between physical scores of SF12 and time spent on self-care. Table 3 shows regression coefficients (β's) of multiple logistic models: (i) without interaction, (ia) with interaction and (ib) with interaction and imputed median values instead of missings in time variables. In both models with interaction, we observed that patient time has a significant (positive) impact on rating of the general health state as "good". However, this association seems to be hidden by the negative interaction term, which is the larger, the larger the physical score of SF12 is. This explains why we did not observe any significant association in model (i), which did not incorporate any interaction. Based on regression coefficients of patient time and interaction term one can easily calculate that for a fixed physical score of SF12 value under 40, patient time increases the chance to rate the health status as "good", while for physical score of SF12 value above 40 patient time had a reverse effect.

Table 1: Description of the study population

Characteristics	Mean±SD, Median (Q1-Q3) or Frequency (%)
Demographic and sociodemographic characteristics	
Age (years)	69.2±10.1, 71.0 (63-77)
Gender (male)	114 (60.0%)
Employment status (yes)	44 (23.2%)
School education	
High (Abitur/Fachabitur/Fachhochschulreife)	31 (16.3%)
Middle (Mittlere Reife/Realschule)	34 (17.9%)
Low (Hauptschulabschluss)	125 (65.8%)
Partner (living together)	138 (72.6%)
Diabetes specific characteristics	
Diabetes duration (n=175)	10.5±8.2, 8.0 (5.0-14.0)
Type of treatment (n=189)	
No antihyperglycaemic medication	30 (15.9%)
Insulin only	10 (5.3%)
Oral antihyperglycaemic medication only	130 (68.8%)
Insulin and oral antihyperglycaemic medication	19 (10.1%)
HbA1c (%) (n=188)	6.7±1.1, 6.5 (6.0-7.1)
< 6.5%	90 (47.9%)
6.5 to < 7.5%	65 (34.6%)
≥ 7.5%	33 (17.6%)
Diabetes-related complications (at least one of 11)	90 (47.4%)
PAID (n=182)	32.3±13.1, 27.5 (21-40)
Lifestyle	
Smoker	18 (9.5%)
BMI (kg/m²)	30.9±5.2, 30.4 (27.2-34.3)
<25 kg/m²	21 (11.1%)
25-<30 kg/m²	67 (35.3%)
30-<35 kg/m²	61 (32.1%)
≥35 kg/m²	41 (21.6%)
Comorbidities	
Myocardial infarction	23 (12.1%)
Angina pectoris	16 (8.4%)
Stroke (n=189)	11 (5.8%)
Cancer	30 (15.8%)
General health status, QoL and patient time	
Rating of the general health status	
Excellent	1 (0.5%)
Very good	12 (6.3%)
Good	135 (71.1%)
Fair	38 (20%)
Poor	4 (2.1%)
QoL: Physical score of SF12	43.2±9.8, 44.5 (35.8-51.3)
QoL: Mental score of SF12	51.6±9.6, 54.3 (46.5-57.9)
Patient time (minutes per week)	121.3±183.9, 44.5 (10-155)
Patient time (minutes per week) with imputations	128.1±191.7, 45.5 (11-170)

BMI body mass index; Q1 the 25%-quartile, Q3 the 75%-Quartile; n=190 patients

Table 2: Odds ratios to rate the general health state as "good"

	Model (i)		Model (ii)		Model (iii)	
	OR (p-value)	**95%-CI**	**OR (p-value)**	**95%-CI**	**OR (p-value)**	**95%-CI**
QoL: Physical score of SF12	**1.23** (<0.0001)	(1.15,1.32)	**1.24** (<0.0001)	(1.15,1.33)	**1.24** (<0.0001)	(1.15,1.34)
QoL: Mental score of SF12	**1.14** (<0.0001)	(1.08,1.20)	**1.13** (<0.0001)	(1.07,1.20)	**1.13** (<0.0001)	(1.06,1.19)
Patient time (minutes per week)	1.003 (0.0692)	(1.00,1.01)	1.002 (0.0898)	(1.00,1.01)	1.003 (0.0600)	(1.00,1.01)
Age (years)			1.03 (0.3738)	(0.97,1.08)	1.05 (0.1967)	(0.98,1.12)
Sex (female vs. male)			0.66 (0.4375)	(0.23,1.88)	0.67 (0.4591)	(0.23,1.95)
Employment status (yes vs. no)					2.83 (0.2660)	(0.45,17.74)
Partner (yes vs. no)					0.68 (0.5575)	(0.19,2.46)
School education (high/middle vs. low)					1.67 (0.4094)	(0.49,5.64)

CI Confidence Intervals
Max-rescaled R-square was 0.64 in (i) and (ii) and 0.65 in (iii).
Area Under the Curve (AUC) was 0.93 in (i), 0.94 in (ii) and (iii).

Table 3: Regression coefficients and odds ratios to rate the general health state as "good" in models with and without interaction term

	Model (i)		Model (ia)		Model (ib)[§]	
	β (p-value)	**OR**	**β (p-value)**	**OR**	**β (p-value)**	**OR**
QoL: Physical score of SF12	**0.2083** (<0.0001)	1.23	**0.2693** (<0.0001)		**0.2684** (<0.0001)	
QoL: Mental score of SF12	**0.1270** (<0.0001)	1.14	**0.1350** (<0.0001)	1.15	**0.1341** (<0.0001)	1.14
Patient time (minutes per week)	0.00261 (0.0692)	1.003	**0.0147** (0.0029)		**0.0140** (0.0004)	
Interaction between Physical score of SF12 and Patient time			**-0.00037** (0.0018)		**-0.00035** (0.0025)	

[§] Sensitivity analysis: missing values in time variables related to particular self-care activities were replaced by the corresponding medians.

OR=exp(β)
Max-rescaled R-square was 0.64 in (i), 0.67 in (ia) and (ib)
Area Under the Curve was 0.93 in (i), 0.94 in (ia) and (ib)

Figure 1 shows OR's to rate general health state as "good" for a person with given physical score of SF12 (y-axis) and patient time (x-axis) compared to a person with median physical score of SF12 (44.5) and median patient time (44.5) for models (i), (ia) and (ib). Estimated OR's are smaller in models with interaction (ia) and (ib) than in model (i) without interaction. Both models with interaction, i.e., (ia) and (ib), yield very similar results despite different handling of missing values. Figure 2 shows the same OR's on the log-scale.

Figure 1: OR's to rate of the general health state as "good" in models (i), (ia) and (ib) (from left to right).

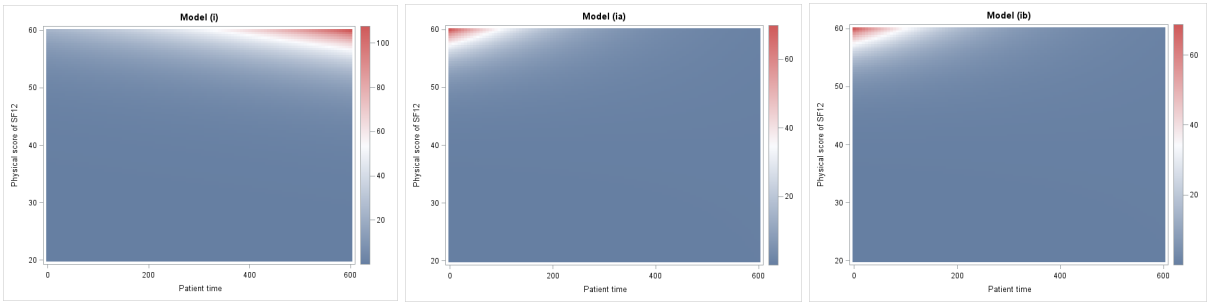
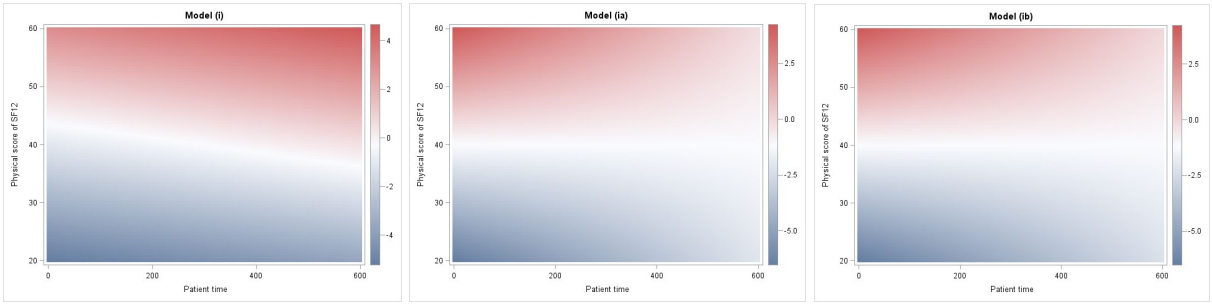


Figure 2: Effects on the log-scale (i.e., log(OR)) to rate the general health state as "good" in models (i), (ia) and (ib) (from left to right).



5. Discussion

5.1 Main findings

In this study we explored possible association between time spent on diabetes self-care and the rating of the health state using regression models. We assumed that if time spent on diabetes self-care leads to lost leisure or to other negative experiences, respondents would (implicitly) consider it in their ratings of the health state in addition to other physical or mental aspects as measured by SF-12 questionnaire.

We did not observe any additional effect of self-care time on the health state ratings in regression models without interaction. However, in the models with interaction we found significant interaction term between physical scores of SF12 and time spent on self-care. In these models, self-care time has a significant impact on the rating of the health state. In particular, for a fixed physical score of SF12 value over 40, more self-care time decreases the chance to rate a health state as "good". That means

that models with interaction imply that persons with highest physical score of SF12 and rather low self-care time have the highest chance to rate their health state as "excellent, very good or good".

Even though the additional effect of self-care time on the health state rating is small, the finding is in line with the assumption that time spent on diabetes self-care competes with other leisure activities and may negatively influence health-related quality of life. The observed positive effect of self-care time on the rating of health state in respondents with physical score of SF12 under 40 may be explained by less "competition" between self-care and other leisure activities in the state of poor health.

5.2 Comparison to other studies

The amount of empirical research on whether respondents include leisure effects of ill-health into health state valuations is limited. Available studies [14, 15, 16] were conducted among respondents from the general public who were asked to value health states on a visual analogue scale (VAS) or using a time trade-off (TTO) method. The respondents were asked afterwards whether they had considered leisure time effects of ill health in their valuations.

The majority of respondents (61%-88%) in available studies stated to spontaneously consider health-related changes in leisure in their health state valuations. However, it is unclear whether this leads to an adequate valuation of lost leisure across various health states: In a study by Brouwer et al, the incorporation of leisure proved to be influential in the valuation with the visual analogue scale (VAS), but only for the most severe health state [15]. In a study by Krol et al using a similar design, there were no significant differences between the valuations of respondents who included or excluded effects on leisure time [14]. In another study by Krol et al using TTO instead of VAS, respondents including leisure time gave lower TTO values to the three health states than respondents who had not included leisure time. The differences, however, were only significant for one health state out of three [16].

Our respondents rated their own health states and we chose to model the possible effect of lost leisure using data on diabetes self-care time which was available for them. Our results are in line with previous

studies and suggest that, if respondents implicitly incorporate time aspects of diabetes self-care in their health state ratings, the effect is rather small.

5.3 Strengths and limitations

Before discussing the implications of our findings, we need to stress that our study was based on a small, however population-based sample of people with diabetes, although it was older, as it was the second follow-up of the baseline representative sample. Health state was rated using a 5-point Likert-type scale, which may be less sensitive to changes in leisure time compared to VAS or TTO valuations. Important limitation of our study is that we cannot exclude the possibility that respondents implicitly considered time aspects of diabetes self-care when answering SF-12 questionnaire. However, this is unlikely because the SF12 focuses rather on function and abilities rather than on other aspects related to ill health such as the lost leisure. Time spent on diabetes self-care is only one aspect of leisure effects due to ill-health. Moreover, lost leisure time because of diabetes self-care may be less of a problem for our respondents (mean age 69 years old) compared to the younger people with more competing demands for time.

5.4 Conclusions and implications for further research

The impact of self-care time in our sample – if respondents indeed implicitly incorporate it into their ratings of the health state – is small and more complex than a simple linear association. If leisure effects of chronic illness should be incorporated into economic evaluation, further research is warranted to ensure that current practice gives sufficient weight to changes in leisure time due to changes in health. Studies in larger samples including participants of different age and also using other health state valuation techniques, such as VAS and TTO may be useful. The important general point here is that the focus of attention that drives our preferences in health states valuations is different from the focus of attention that explains the intensity of our experiences [22]. Specifically, one has to ask whether inclusion of leisure time effects by means of preference-based health-related quality of life instruments

in the denominator of the cost-effectiveness ratio is sufficient or whether new ways (e.g. measures of experienced utility or monetary valuation) to include leisure in economic evaluations have to be found.

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