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ORIGINAL RESEARCH

How do patients with diabetes report their comorbidities? Comparison with administrative data

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Aims: Patients with diabetes are probably often unaware of their comorbidities. We estimated agreement between self-reported comorbidities and administrative data.

Methods: In a random sample of 464 diabetes patients, data from a questionnaire asking about the presence of 14 comorbidities closely related to diabetes were individually linked with statutory health insurance data.

Results: Specificities were >97%, except cardiac insufficiency (94.5%), eye diseases (93.8%), peripheral arterial disease (92.6%), hypertension (90.9%), and peripheral neuropathy (85.8%). Sensitivities were <60%, except amputation (100%), hypertension (83.1%), and myocardial infarction (67.2%). A few positive predictive values were >90% (hypertension, myocardial infarction, and eye disease), and six were below 70%. Six negative predictive values were >90%, and two <70% (hypertension and eye disease). Total agreement was between 42.7% (eye disease) and 100% (dialysis and amputation). Overall, substantial agreement was observed for three morbidities (kappa 0.61–0.80: hypertension, myocardial infarction, and amputation). Moderate agreement (kappa 0.41–0.60) was estimated for angina pectoris, heart failure, stroke, peripheral neuropathy, and kidney disease. Factors associated with agreement were the number of comorbidities, diabetes duration, age, sex, and education.

Conclusions: Myocardial infarction and amputation were well reported by patients as comorbidities; eye diseases and foot ulceration rather poorly, particularly in older, male, or less educated patients. Patient information needs improving.

Keywords: diabetes comorbidities, self-report, agreement, patient information

Introduction

The prevalence of diabetes mellitus has increased substantially and in 2015 reached 8.8%, which corresponds to 415 million patients globally. Diabetes is a major cause of morbidity and mortality and is, in economic terms, extremely costly.[1]

One of the largest problems in diabetes is the high risk of diabetes-associated comorbidities, such as foot ulceration, retinopathy, chronic kidney disease, and cardiovascular diseases. These complications crucially affect a patient's health-related quality of life, health care utilization, health care costs, and life expectancy.[1–6] However, patients are probably often unaware of their comorbidities.[7] For instance, 32% of people with diabetes do not realize that heart disease is a common complication of diabetes.[7] Seventy-seven percent of people diagnosed with diabetes and peripheral neuropathy were unaware of their condition.[8] This is of high relevance for several reasons: 1) Knowledge about comorbidities is crucial for effective self-management.[9] According to Duggan and Bates[10], diabetic patients have a substantial need for information,

but a large proportion of patients with diabetes have stated that they are not well informed about the disease.[11] Hence, more effort should be made to provide diabetic patients with effective information. 2) In most observational as well as interventional or health economic studies, comorbidity has to be assessed as a relevant outcome or confounder. Very often, data concerning comorbidities are assessed by asking patients, that is, it is self-reported. Incomplete knowledge about their own comorbidities would result in invalid data.

A number of studies analyzed the agreement between self-reported and routine data-based comorbidities in different patient populations, and found it to differ largely, depending on the comorbidity and patients' characteristics.[12–15] However, in patients with diabetes, no study has as yet investigated the level of agreement between different data sources reporting diabetes-associated comorbidities.

The aim of our study was 1) to estimate the agreement between patients' self-reported and health insurance data with regard to comorbidity, and 2) to evaluate the factors associated with the level of agreement.

Methods
Study design
We performed an observational study. Comorbidity data were obtained using a written questionnaire and then linked to statutory health insurance (SHI) data in order to examine the agreement between the data sources.

Study population
Patients were recruited in an outpatient clinical center specializing in diabetes treatment. This center treats about 3,500 patients with diabetes in a defined region of Western Germany. We selected all the patients who were members of the pronova health insurance company (pronova BKK), because data from this SHI had been made available for our study. Pronova BKK covers a large proportion of the inhabitants in the study region and about 30% of the patients with diabetes at our clinical study center. Of these patients insured with the pronova BKK, 737 were randomly selected and were contacted by telephone to ask if they would be willing to participate in our study. Five hundred agreed (response 67.8%). Of these 500 patients, two had to be excluded because they were employees of the BKK, and a further 34 because of missing data, resulting in a population of 464 patients for inclusion in the analyses.

Ethical approval for the study was granted by the Ethics Committee, Faculty of Medicine, Heinrich-Heine University Düsseldorf (references 3455 and 3595). All patients have provided written informed consent for participating in this study.

Data sources and variables
Self-report questionnaire
The questionnaire used for the study was developed to conduct trial economic evaluations of interventions for patients with diabetes.[16,17] First, available health care utilization and comorbidity questionnaires were reviewed and then a new questionnaire more suitable for reflecting the specific aspects of diabetes was elaborated in close cooperation with clinical experts. We conducted interviews with patients from self-help groups and general practitioners in order to evaluate and further improve the questionnaire, using cognitive techniques such as paraphrasing to check whether the questions were consistently understood and could be answered by all the respondents. The instrument has been modified accordingly and published in its final version.[18]

The questionnaire asks about the presence of comorbidities, taken from a list of 35, within the previous 12 months ("Has a doctor diagnosed the following condition?"). Of these 35 comorbidities, 14 were defined as closely associated with diabetes: hypertension, peripheral arterial disease, angina pectoris, myocardial infarction (MI), heart failure, impaired cerebral blood flow, stroke, transient ischemic attack (TIA), eye diseases, peripheral neuropathy (lower extremity), foot ulcerations, amputations, kidney disease, and dialysis. The exact question and the 35 comorbidities are presented in the Supplementary material.

The assessment of self-reports was conducted between March 2011 and November 2012. Patients received the printed questionnaire during a routine physician visit and filled it out by themselves. After the patients had filled out the questionnaire, it was checked immediately by a member of the study team, and missing or implausible data were clarified.

Besides comorbidities, the questionnaire assessed a number of sociodemographic variables: age, sex, education (highest school and occupational degree according to Hoffmeyer-Zlotnik and Warner, dichotomized by the cut point ≥5),[19] and income (net wage household income, dichotomized by the cut point >1,250 EUR).[20] Furthermore, the EQ-5D was used to assess health-related quality of life.[21]

Health insurance data
In Germany, SHIs cover the vast majority of health services (ambulatory services, emergency visits, hospitalization, medication, and so on). All health service data are available for every individual insurant, along with exact dates and diagnoses. Every diagnosis is coded according to the International Statistical Classification of Diseases (ICD10).

For the present analysis, all SHI data were available from the study population during the 12 months before the assessment of the patients' comorbidities. Diagnoses concerning the comorbidities of interest were selected by one researcher (JH), and checked in full by a second (HA). The number of chronic diseases (later dichotomized using the cut point >5) was determined by the following rule[22]: diabetes plus 35 diseases from the questionnaire were considered as candidates for chronic diseases. A disease was counted as chronic if the corresponding ICD10 code appears at least in three out of four quarters prior to the patient's assessment.

Statistical analyses

Description of the study population

The characteristics of the study population were described using means (SD) and proportions as appropriate. Prevalence of diseases from health insurance data and from self-reports were estimated along with 95% CIs.

Agreement between the data sources

We estimated the agreement between self-report and SHI data by using the following probability measures, including 95% CIs: sensitivity (ratio of correctly reported positive SHI data/all positive SHI), specificity (ratio of correctly reported negative SHI data/all negative SHI data), positive predictive value (PPV) (ratio of positive SHI data/all positives reported by the questionnaire), negative predictive value (NPV) (ratio negative SHI data/all negatives reported by the questionnaire), and total agreement (ratio of correctly reported positive or negative SHI data/total reports or SHI data).

The chance-corrected agreement between self-reported questionnaire data and SHI data was estimated by kappa coefficients.[23] The ranges of kappa values were interpreted as follows[24]: ≤0.40 poor-to-fair agreement, 0.41–0.60 moderate agreement, 0.61–0.80 substantial agreement, and 0.81–1.00 excellent agreement.

A stratified analysis of sensitivity, specificity, and total agreement was conducted for each condition according to age (continuous), sex, education level (according to the Hoffmeyer-Zlotnik/Warner Matrix),[25] income, general health (assessed by the visual analog scale of the EQ-5D),[21] diabetes duration (≥10 versus <10 years, extracted from the practice documentation), and number of chronic comorbidities derived by SHI data. Differences across strata were examined by univariate logistic regression (described below). Amputation and dialysis were excluded from stratified analyses because of low prevalence and small differences between insurance data and self-reports.

Logistic regression

Logistic regression models were fitted to estimate associations between the above-mentioned patient characteristics and total agreement between diagnoses from health insurance and self-reports for each disease, with the exception of amputations and dialyses. First, unadjusted odds ratios (95% CIs) were estimated from univariate models. Additionally, odds ratios were adjusted by fitting multivariate models, including age (≥65 years), sex, education level (≥5), income (>1,250 EUR), general health (assessed by the visual analog scale of the EQ-5D, >75 versus ≤75), diabetes duration (≥10 versus <10 years), and number of chronic comorbidities (>5) simultaneously.

All analyses were performed using the Statistical Analysis Systems SAS (SAS for Windows running on the X64_8PRO platform, Release 9.4 TS1M3 and TS1M4; SAS Institute Inc., Cary, NC, USA). A two-sided alpha level of 0.05 was considered statistically significant.

Results

Population

The characteristics of the cohort are described in Table 1. The mean age was about 60 years, and 61% were male. Higher

Table 1 Patient characteristics

Variable	Proportion/mean (n=464)
Sex	
Male (n, %)	281 (60.6)
Female (n, %)	183 (39.4)
Age (years)	
<65 (n, %)	277 (59.7)
≥65 (n, %)	187 (40.3)
Age (years), mean±SD (range)	60.1±14.4 (18–89)
Diabetes type (3 missing)	
Type 1 (n, %)	107 (23.2)
Type 2 (n, %)	354 (76.8)
Diabetes duration (years)	
Mean±SD (range)	13.5±10.5 (0–59)
≥10 years (n, %)	278 (59.9)
Equivalized disposable income (EUR, 53 missing)	
≤1250 EUR (n, %)	241 (58.6)
>1250 EUR (n, %)	170 (41.4)
Education (%, 7 missing)	
Low (n, %)	248 (54.3)
Higher (n, %)	209 (45.7)
EQ-5D-VAS (%, 2 missing)[a]	
≤75 (n, %)	266 (57.6)
>75 (n, %)	196 (42.4)
Number of chronic diseases (%)	
≤5 (n, %)	261 (56.3)
>5 (n, %)	203 (43.8)

Notes: [a]Visual analog scale of the EuroQol quality-of-life questionnaire.

and lower socioeconomic positions were almost equally distributed. The mean diabetes duration was 13.5 years, and about three quarters had type 2 diabetes. More than 40% had more than five comorbidities besides their diabetes. Table 2 presents numbers and prevalence of the assessed comorbidities. Compared with the individuals who did not participate in the study (from the random sample of 737 pronova BKK patients), the percentage of men was slightly, but not significantly, higher in the responders. The age distribution using 5-year grouping was similar in responders and nonresponders (data not shown).

Agreement

The agreement measures of the different comorbidities are presented in Table 3. High specificities above 97% were in

the majority; exceptions (<97%) were cardiac insufficiency (94.5%), eye diseases (93.8%), peripheral arterial disease (92.6%), hypertension (90.9%), and peripheral neuropathy (85.8%). Sensitivities were below 60% for 10 comorbidities, above 60%, only amputation (100%), hypertension (83.1%), and MI (67.2%) were above 60%. Depending on prevalence (Table 1), specificities and sensitivities can be transformed into estimates of PPVs and NPVs (Table 2). Only a few PPVs were above 90% (hypertension, MI, and eye disease). On the other hand, six PPVs were below 70%. Six NPVs >90% were observed; only two were below 70% (hypertension and eye diseases). Total agreement was estimated between 42,7% (eye diseases) and about 100 % (dialysis and amputation). However, these results also depend on the prevalence. For instance, total agreement was 96.8% for TIA, but a kappa

Table 2 Disease prevalence in the study population

Comorbidities	Prevalence (95% confidence interval)			
	n (GKV)	n (self-reported)	GKV	Self-documentation
Hypertension	354	304	76.3 (72.2–80.1)	65.5 (61.0–69.8)
Peripheral arterial disease	124	68	26.7 (22.7–31.0)	14.7 (11.6–18.2)
Angina pectoris	134	56	28.9 (24.8–33.2)	12.1 (9.2–15.4)
Myocardial infarction	58	43	12.5 (9.6–15.9)	9.3 (6.8–12.3)
Heart failure	79	57	17.0 (13.7–20.8)	12.3 (9.4–15.6)
Impaired cerebral blood flow	57	11	12.3 (9.4–15.6)	2.4 (1.2–4.2)
Stroke/apoplexy	42	19	9.1 (6.6–12.0)	4.1 (2.5–6.3)
Transient ischemic attack	7	10	1.5 (0.6–3.1)	2.2 (1.0–3.9)
Eye diseases	368	114	79.3 (75.3–82.9)	24.6 (20.7–28.7)
Peripheral neuropathy (leg)	210	157	45.3 (40.7–49.9)	33.8 (29.5–38.3)
Foot ulceration	58	29	12.5 (9.6–15.9)	6.3 (4.2–8.9)
Lower-extremity amputation (legs)	8	13	1.7 (0.7–3.4)	2.8 (1.5–4.7)
Kidney disease	130	61	28.0 (24.0–32.3)	13.1 (10.2–16.6)
Dialysis	0	0	0.0 (0.0–0.8)	0.0 (0.0–0.8)

Note: GKV, Statutory health insurance.

Table 3 Sensitivity, specificity, PPV, NPV, kappa, and total agreement

Disease	Sensitivity (%) (95% CI)	Specificity (%) (95% CI)	PPV (%) (95% CI)	NPV (%) (95% CI)	Kappa (95% CI)	Total agreement (%) (95% CI)
Hypertension	83.1 (78.7–86.8)	90.9 (83.9–95.6)	96.7 (94.0–98.4)	62.5 (54.5–70.0)	0.64 (0.56–0.71)	84.9 (81.3–88.0)
Peripheral arterial disease	34.7 (26.4–43.7)	92.6 (89.3–95.2)	63.2 (50.7–74.6)	79.5 (75.2–83.4)	0.32 (0.22–0.42)	77.2 (73.1–80.9)
Angina pectoris	37.3 (29.1–46.1)	98.2 (96.1–99.3)	89.3 (78.1–96.0)	79.4 (75.2–83.2)	0.43 (0.34–0.52)	80.6 (76.7–84.1)
Myocardial infarction	67.2 (53.7–79.0)	99.0 (97.5–99.7)	90.7 (77.9–97.4)	95.5 (93.0–97.3)	0.75 (0.65–0.84)	95.0 (92.7–96.8)
Heart failure	45.6 (34.3–57.2)	94.5 (91.8–96.6)	63.2 (49.3–75.6)	89.4 (86.0–92.2)	0.45 (0.34–0.56)	86.2 (82.7–89.2)
Impaired cerebral blood flow	12.3 (5.1–23.7)	99.0 (97.5–99.7)	63.6 (30.8–89.1)	89.0 (85.7–91.7)	0.17 (0.05–0.30)	88.4 (85.1–91.1)
Stroke/apoplexy	38.1 (23.6–54.4)	99.3 (97.9–99.9)	84.2 (60.4–96.6)	94.2 (91.6–96.1)	0.50 (0.34–0.65)	93.8 (91.1–95.8)
Transient ischemic attack	14.3 (0.4–57.9)	98.0 (96.3–99.1)	10.0 (0.3–44.5)	98.7 (97.1–99.5)	0.10 (−0.11–0.31)	96.8 (94.7–98.2)
Eye diseases	29.3 (24.7–34.3)	93.8 (86.9–97.7)	94.7 (88.9–98.0)	25.7 (21.2–30.6)	0.12 (0.08–0.16)	42.7 (38.1–47.3)
Peripheral neuropathy (leg)	57.6 (50.6–64.4)	85.8 (80.9–89.9)	77.1 (69.7–83.4)	71.0 (65.6–76.0)	0.44 (0.36–0.52)	73.1 (68.8–77.0)
Foot ulcerations	32.8 (21.0–46.3)	97.5 (95.5–98.8)	65.5 (45.7–82.1)	91.0 (87.9–93.5)	0.39 (0.25–0.52)	89.4 (86.3–92.1)
Lower-extremity amputation	100.0 (63.1–100.0)	98.9 (97.5–99.6)	61.5 (31.6–86.1)	100.0 (99.2–100.0)	0.76 (0.55–0.96)	98.9 (97.5–99.6)
Kidney disease	40.0 (31.5–49.0)	97.3 (94.9–98.8)	85.2 (73.8–93.0)	80.6 (76.4–84.4)	0.45 (0.35–0.54)	81.3 (77.4–84.7)
Dialysis	–	100.0 (99.2–100.0)	–	100.0 (99.2–100.0)	–	100.0 (99.2–100.0)

Abbreviations: NPV, negative predictive value; PPV, positive predictive value.

of 0.10 corresponds only to poor agreement (sensitivity 14.3%, prevalence 1.5%). Overall, substantial agreement was observed for three comorbidities, corresponding to kappa 0.61–0.80: hypertension, MI, amputation. A moderate agreement was estimated for five comorbidities (kappa 0.41–0.60: angina pectoris, heart failure, stroke, peripheral neuropathy, kidney disease).

Associations with agreement: results from stratifications and regression analysis

Associations of participant characteristics with strengths of agreement between self-reports and health insurance data are shown in Tables 4 and 5. In univariate analyses, higher age,

Table 4 Sensitivity, specificity, and total agreement stratified by patient characteristics

Subgroups (strata)	Hypertension			Peripheral arterial disease			Angina pectoris		
	Sensitivity (95% CI)	Specificity (95% CI)	Agreement (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)	Agreement (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)	Agreement (95% CI)
Age <65 years	84.3 (78.1–89.3)	91.9 (84.7–96.4)	87.0 (82.5–90.7)	25.0 (12.7–41.2)	93.7 (89.8–96.4)	83.8 (78.9–87.9)	34.8 (21.4–50.2)	99.1 (96.9–99.9)	88.4 (84.1–92.0)
Age ≥65 years	81.8 (75.3–87.2)	81.8 (48.2–97.7)	81.8 (75.5–87.1)	39.3 (28.8–50.5)	90.3 (82.9–95.2)	67.4 (60.2–74.0)	38.6 (28.4–49.6)	96.0 (90.0–98.9)	69.0 (61.8–75.5)
Female	83.5 (76.2–89.2)	93.2 (81.3–98.6)	85.8 (79.9–90.5)	26.8 (14.2–42.9)	93.0 (87.4–96.6)	78.1 (71.4–83.9)	31.7 (18.1–48.1)	97.9 (94.0–99.6)	83.1 (76.8–88.2)
Male	82.8 (77.1–87.6)	89.4 (79.4–95.6)	84.3 (79.6–88.4)	38.6 (28.1–49.9)	92.4 (87.8–95.7)	76.5 (71.1–81.3)	39.8 (29.8–50.5)	98.4 (95.4–99.7)	79.0 (73.8–83.6)
Lower education	82.3 (76.6–87.2)	81.8 (64.5–93.0)	82.3 (76.9–86.8)	40.5 (29.9–51.7)	89.6 (83.9–93.8)	73.0 (67.0–78.4)	35.6 (26.4–45.8)	96.6 (92.2–98.9)	71.8 (65.7–77.3)
Higher education	83.8 (76.5–89.6)	95.9 (88.5–99.1)	88.0 (82.9–92.1)	23.1 (11.1–39.3)	95.9 (91.7–98.3)	82.3 (76.4–87.2)	42.4 (25.5–60.8)	100.0 (97.9–100.0)	90.9 (86.2–94.4)
Lower income	82.4 (76.1–87.5)	87.0 (75.1–94.6)	83.4 (78.1–87.9)	33.3 (22.2–46.0)	89.7 (84.2–93.8)	74.3 (68.3–79.7)	41.9 (30.5–53.9)	98.2 (94.8–99.6)	80.9 (75.4–85.7)
Higher income	82.4 (74.6–88.6)	93.3 (81.7–98.6)	85.3 (79.1–90.3)	33.3 (19.6–49.5)	96.1 (91.1–98.7)	80.6 (73.8–86.2)	39.5 (25.0–55.6)	98.4 (94.4–99.8)	83.5 (77.1–88.8)
VAS ≤75	83.5 (78.0–88.1)	92.9 (80.5–98.5)	85.0 (80.1–89.0)	37.1 (27.1–48.0)	87.6 (81.8–92.0)	70.7 (64.8–76.1)	45.3 (35.0–55.8)	97.7 (94.1–99.4)	78.9 (73.5–83.7)
VAS >75	82.8 (75.1–88.9)	89.7 (79.9–95.8)	85.2 (79.4–89.9)	29.4 (15.1–47.5)	98.1 (94.7–99.6)	86.2 (80.6–90.7)	17.9 (7.5–33.5)	98.7 (95.5–99.8)	82.7 (76.6–87.7)
No. of chronic diseases ≤5	85.1 (78.4–90.3)	90.7 (83.5–95.4)	87.4 (82.7–91.1)	38.2 (22.2–56.4)	95.6 (92.0–97.9)	88.1 (83.6–91.8)	32.1 (15.9–52.4)	99.6 (97.6–100.0)	92.3 (88.4–95.3)
No. of chronic diseases >5	81.5 (75.4–86.6)	100.0 (29.2–100.0)	81.8 (75.8–86.8)	33.3 (23.7–44.1)	86.7 (79.1–92.4)	63.1 (56.0–69.7)	38.7 (29.4–48.6)	94.8 (88.4–98.3)	65.5 (58.5–72.0)
Diabetes duration <10 years	84.2 (76.9–90.0)	92.5 (81.8–97.9)	86.6 (80.8–91.1)	35.0 (15.4–59.2)	93.4 (88.5–96.6)	87.1 (81.4–91.6)	51.2 (35.1–67.1)	100.0 (97.5–100.0)	89.2 (83.9–93.3)
Diabetes duration ≥10 years	82.4 (76.7–87.1)	89.5 (78.5–96.0)	83.8 (78.9–87.9)	34.6 (25.6–44.6)	92.0 (86.9–95.5)	70.5 (64.8–75.8)	31.2 (22.0–41.6)	96.8 (93.1–98.8)	74.8 (69.3–79.8)
	Myocardial infarction			**Heart failure**			**Impaired cerebral blood flow**		
Age <65 years	71.4 (47.8–88.7)	99.2 (97.2–99.9)	97.1 (94.4–98.7)	25.0 (8.7–49.1)	97.3 (94.5–98.9)	92.1 (88.2–95.0)	7.7 (0.2–36.0)	98.9 (96.7–99.8)	94.6 (91.2–96.9)
Age ≥65 years	64.9 (47.5–79.8)	98.7 (95.3–99.8)	92.0 (87.1–95.4)	52.5 (39.1–65.7)	89.1 (82.3–93.9)	77.5 (70.9–83.3)	13.6 (5.2–27.4)	99.3 (96.2–100.0)	79.1 (72.6–84.7)
Female	76.9 (46.2–95.0)	99.4 (96.8–100.0)	97.8 (94.5–99.4)	51.9 (31.9–71.3)	97.4 (93.6–99.3)	90.7 (85.5–94.5)	4.2 (0.1–21.1)	99.4 (96.5–100.0)	86.9 (81.1–91.4)
Male	64.4 (48.8–78.1)	98.7 (96.3–99.7)	93.2 (89.6–95.9)	42.3 (28.7–56.8)	92.6 (88.4–95.6)	83.3 (78.4–87.4)	18.2 (7.0–35.5)	98.8 (96.5–99.7)	89.3 (85.1–92.7)
Lower education	61.9 (45.6–76.4)	99.5 (97.3–100.0)	93.1 (89.3–96.0)	44.8 (31.7–58.5)	92.1 (87.3–95.5)	81.0 (75.6–85.7)	13.2 (4.4–28.1)	99.0 (96.6–99.9)	85.9 (80.9–90.0)
Higher education	81.3 (54.4–96.0)	98.4 (95.5–99.7)	97.1 (93.9–98.9)	50.0 (27.2–72.8)	96.8 (93.2–98.8)	92.3 (87.9–95.6)	10.5 (1.3–33.1)	98.9 (96.2–99.9)	90.9 (86.2–94.4)
Lower income	68.4 (51.3–82.5)	99.5 (97.3–100.0)	94.6 (91.0–97.1)	43.8 (29.5–58.8)	94.3 (90.0–97.1)	84.2 (79.0–88.6)	12.5 (2.7–32.4)	98.2 (95.3–99.5)	89.6 (85.1–93.2)

(*Continued*)

Table 4 (*Continued*)

Subgroups (strata)	Myocardial infarction			Heart failure			Impaired cerebral blood flow		
	Sensitivity (95% CI)	Specificity (95% CI)	Agreement (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)	Agreement (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)	Agreement (95% CI)
Higher income	64.7 (38.3–85.8)	98.7 (95.4–99.8)	95.3 (90.9–97.9)	55.0 (31.5–76.9)	94.7 (89.8–97.7)	90.0 (84.5–94.1)	15.4 (4.4–34.9)	100.0 (97.5–100.0)	87.1 (81.1–91.7)
VAS ≤75	65.9 (50.1–79.5)	99.1 (96.8–99.9)	93.6 (90.0–96.2)	51.8 (38.0–65.3)	92.4 (87.9–95.6)	83.8 (78.8–88.0)	11.9 (4.0–25.6)	98.2 (95.5–99.5)	84.6 (79.7–88.7)
VAS >75	71.4 (41.9–91.6)	98.9 (96.1–99.9)	96.9 (93.5–98.9)	30.4 (13.2–52.9)	97.1 (93.4–99.1)	89.3 (84.1–93.2)	13.3 (1.7–40.5)	100.0 (98.0–100.0)	93.4 (88.9–96.4)
No. of chronic diseases ≤5	85.7 (42.1–99.6)	98.8 (96.6–99.8)	98.5 (96.1–99.6)	23.1 (5.0–53.8)	98.8 (96.5–99.7)	95.0 (91.6–97.3)	0.0 (0.0–24.7)	99.6 (97.8–100.0)	94.6 (91.2–97.0)
No. of chronic diseases >5	64.7 (50.1–77.6)	99.3 (96.4–100.0)	90.6 (85.8–94.3)	50.0 (37.4–62.6)	86.9 (80.0–92.0)	74.9 (68.3–80.7)	15.9 (6.6–30.1)	98.1 (94.6–99.6)	80.3 (74.1–85.5)
Diabetes duration <10 years	73.7 (48.8–90.9)	98.8 (95.7–99.9)	96.2 (92.4–98.5)	37.5 (18.8–59.4)	92.0 (86.7–95.7)	84.9 (79.0–89.8)	0.0 (0.0–33.6)	99.4 (96.9–100.0)	94.6 (90.3–97.4)
Diabetes duration ≥10 years	64.1 (47.2–78.8)	99.2 (97.0–99.9)	94.2 (90.8–96.7)	49.1 (35.4–62.9)	96.4 (93.1–98.4)	87.1 (82.5–90.8)	14.6 (6.1–27.8)	98.7 (96.2–99.7)	84.2 (79.3–88.3)
	Stroke/Apoplexy			**Transient ischemic attack**			**Eye diseases**		
Age <65 years	41.7 (15.2–72.3)	99.2 (97.3–99.9)	96.8 (93.9–98.5)	0.0 (0.0–97.5)	97.8 (95.3–99.2)	97.5 (94.9–99.0)	19.4 (14.2–25.6)	97.4 (90.8–99.7)	40.8 (35.0–46.8)
Age ≥65 years	36.7 (19.9–56.1)	99.4 (96.5–100.0)	89.3 (84.0–93.3)	16.7 (0.4–64.1)	98.3 (95.2–99.7)	95.7 (91.7–98.1)	41.3 (33.8–49.2)	80.0 (56.3–94.3)	45.5 (38.2–52.9)
Female	33.3 (11.8–61.6)	99.4 (96.7–100.0)	94.0 (89.5–97.0)	0.0 (0.0–70.8)	98.9 (96.0–99.9)	97.3 (93.7–99.1)	29.8 (22.6–37.8)	100.0 (89.1–100.0)	42.1 (34.8–49.6)
Male	40.7 (22.4–61.2)	99.2 (97.2–99.9)	93.6 (90.1–96.2)	25.0 (0.6–80.6)	97.5 (94.9–99.0)	96.4 (93.6–98.3)	29.0 (23.1–35.6)	90.6 (80.7–96.5)	43.1 (37.2–49.1)
Lower education	35.5 (19.2–54.6)	99.1 (96.7–99.9)	91.1 (86.9–94.4)	0.0 (0.0–45.9)	97.9 (95.2–99.3)	95.6 (92.2–97.8)	33.7 (27.2–40.6)	90.7 (77.9–97.4)	43.5 (37.3–50.0)
Higher education	45.5 (16.7–76.6)	99.5 (97.2–100.0)	96.7 (93.2–98.6)	100.0 (2.5–100.0)	98.1 (95.1–99.5)	98.1 (95.2–99.5)	24.8 (18.3–32.4)	96.2 (86.8–99.5)	42.6 (35.8–49.6)
Lower income	47.8 (26.8–69.4)	99.1 (96.7–99.9)	94.2 (90.4–96.8)	50.0 (1.3–98.7)	97.9 (95.2–99.3)	97.5 (94.7–99.1)	32.5 (25.9–39.6)	97.9 (88.7–99.9)	45.2 (38.8–51.7)
Higher income	27.3 (6.0–61.0)	99.4 (96.5–100.0)	94.7 (90.2–97.6)	0.0 (0.0–60.2)	98.2 (94.8–99.6)	95.9 (91.7–98.3)	23.9 (16.9–32.0)	91.7 (77.5–98.2)	38.2 (30.9–46.0)
VAS ≤75	40.6 (23.7–59.4)	99.1 (96.9–99.9)	92.1 (88.2–95.0)	14.3 (0.4–57.9)	97.3 (94.5–98.9)	95.1 (91.8–97.4)	33.8 (27.5–40.5)	90.0 (78.2–96.7)	44.4 (38.3–50.6)
VAS >75	30.0 (6.7–65.2)	99.5 (97.0–100.0)	95.9 (92.1–98.2)	Not estimable	99.0 (96.4–99.9)	99.0 (96.4–99.9)	23.2 (16.7–30.7)	97.8 (88.2–99.9)	40.3 (33.4–47.5)
No. of chronic diseases ≤5	28.6 (3.7–71.0)	99.2 (97.2–99.9)	97.3 (94.6–98.9)	Not estimable	98.9 (96.7–99.8)	98.9 (96.7–99.8)	16.8 (11.7–22.9)	97.4 (90.8–99.7)	40.2 (34.2–46.5)
No. of chronic diseases >5	40.0 (23.9–57.9)	99.4 (96.7–100.0)	89.2 (84.1–93.1)	14.3 (0.4–57.9)	96.9 (93.5–98.9)	94.1 (89.9–96.9)	42.1 (34.8–49.6)	80.0 (56.3–94.3)	45.8 (38.8–52.9)
Diabetes duration <10 years	62.5 (24.5–91.5)	98.3 (95.2–99.7)	96.8 (93.1–98.8)	0.0 (0.0–84.2)	98.4 (95.3–99.7)	97.3 (93.8–99.1)	15.2 (9.5–22.4)	92.6 (82.1–97.9)	37.6 (30.7–45.0)
Diabetes duration ≥10 years	32.4 (17.4–50.5)	100.0 (98.5–100.0)	91.7 (87.8–94.7)	20.0 (0.5–71.6)	97.8 (95.3–99.2)	96.4 (93.5–98.3)	37.3 (31.1–43.8)	95.2 (83.8–99.4)	46.0 (40.1–52.1)
	Peripheral neuropathy (leg)			**Foot ulcerations**			**Kidney disease**		
Age <65 years	51.0 (40.6–61.4)	87.3 (81.5–91.8)	74.7 (69.2–79.7)	21.1 (6.1–45.6)	97.7 (95.0–99.1)	92.4 (88.6–95.2)	38.3 (24.5–53.6)	98.7 (96.2–99.7)	88.4 (84.1–92.0)
Age ≥65 years	63.2 (53.6–72.0)	82.2 (71.5–90.2)	70.6 (63.5–77.0)	38.5 (23.4–55.4)	97.3 (93.2–99.3)	85.0 (79.1–89.8)	41.0 (30.3–52.3)	94.2 (87.9–97.9)	70.6 (63.5–77.0)
Female	54.9 (42.7–66.8)	84.8 (76.8–90.9)	73.2 (66.2–79.5)	14.3 (1.8–42.8)	97.6 (94.1–99.4)	91.3 (86.2–94.9)	35.0 (20.6–51.7)	96.5 (92.0–98.9)	83.1 (76.8–88.2)
Male	59.0 (50.3–67.3)	86.6 (79.9–91.7)	73.0 (67.4–78.1)	38.6 (24.4–54.5)	97.5 (94.6–99.1)	88.3 (83.9–91.8)	42.2 (31.9–53.1)	97.9 (94.7–99.4)	80.1 (74.9–84.6)
Lower education	63.5 (54.4–71.9)	80.3 (72.2–87.0)	71.8 (65.7–77.3)	32.5 (18.6–49.1)	97.6 (94.5–99.2)	87.1 (82.3–91.0)	38.8 (28.4–50.0)	97.5 (93.8–99.3)	77.4 (71.7–82.5)
Higher education	49.4 (38.2–60.6)	90.5 (84.0–95.0)	74.2 (67.7–80.0)	33.3 (13.3–59.0)	97.4 (94.0–99.1)	91.9 (87.3–95.2)	41.9 (27.0–57.9)	97.0 (93.1–99.0)	85.6 (80.1–90.1)

Table 4 (*Continued*)

Subgroups (strata)	Peripheral neuropathy (leg)			Foot ulcerations			Kidney disease		
	Sensitivity	Specificity	Agreement	Sensitivity	Specificity	Agreement	Sensitivity	Specificity	Agreement
Lower income	60.3	85.6	73.4	36.1	97.1	88.0	37.8	97.0	78.8
	(50.8–69.3)	(78.2–91.2)	(67.4–78.9)	(20.8–53.8)	(93.7–98.9)	(83.2–91.8)	(26.8–49.9)	(93.2–99.0)	(73.1–83.8)
Higher income	54.4	85.3	72.9	20.0	98.1	91.2	41.0	98.5	85.3
	(41.9–66.5)	(76.9–91.5)	(65.6–79.5)	(4.3–48.1)	(94.4–99.6)	(85.9–95.0)	(25.6–57.9)	(94.6–99.8)	(79.1–90.3)
VAS ≤75	58.8	78.8	67.7	32.5	96.0	86.5	45.9	95.6	79.7
	(50.4–66.8)	(70.3–85.8)	(61.7–73.3)	(18.6–49.1)	(92.6–98.2)	(81.8–90.3)	(35.0–57.0)	(91.5–98.1)	(74.4–84.4)
VAS >75	55.7	91.9	80.6	33.3	99.4	93.4	29.5	99.3	83.7
	(42.4–68.5)	(85.9–95.9)	(74.4–85.9)	(13.3–59.0)	(96.9–100.0)	(88.9–96.4)	(16.8–45.2)	(96.4–100.0)	(77.7–88.6)
No. of chronic diseases ≤5	47.4	88.5	76.2	25.0	97.6	94.3	23.5	98.2	88.5
	(36.0–59.1)	(83.0–92.8)	(70.6–81.3)	(5.5–57.2)	(94.8–99.1)	(90.7–96.7)	(10.7–41.2)	(95.5–99.5)	(84.0–92.1)
No. of chronic diseases >5	63.6	78.9	69.0	34.8	97.5	83.3	45.8	95.3	71.9
	(54.8–71.8)	(67.6–87.7)	(62.1–75.3)	(21.4–50.2)	(93.6–99.3)	(77.4–88.1)	(35.6–56.3)	(89.4–98.5)	(65.2–78.0)
Diabetes duration <10 years	44.4	83.7	70.4	25.0	97.8	94.6	44.4	96.7	86.6
	(31.9–57.5)	(76.0–89.8)	(63.3–76.9)	(3.2–65.1)	(94.3–99.4)	(90.3–97.4)	(27.9–61.9)	(92.4–98.9)	(80.8–91.1)
Diabetes duration ≥10 years	63.3	87.8	74.8	34.0	97.4	86.0	38.3	97.8	77.7
	(54.9–71.1)	(80.9–92.9)	(69.3–79.8)	(21.2–48.8)	(94.4–99.0)	(81.3–89.8)	(28.5–48.9)	(94.5–99.4)	(72.3–82.5)

Notes: Non-estimable sensitivities: no diseased patients in the subgroup. Patients with missing values excluded from analyses.
Abbreviation: VAS, visual analog scale.

male sex, having more than five chronic comorbidities, and long diabetes duration (≥10 years) were associated with a lower agreement in several comorbidities (exception: higher agreement for heart failure after longer diabetes duration), and higher education and a better quality of life with higher agreement. Additionally, stratified sensitivities and specificities are shown in Table 3. After adjustment in multivariate analyses, only a few significant associations remained. Most associations were seen as having more than five chronic comorbidities. This was associated with a lower agreement for peripheral vascular disease, angina pectoris, MI, heart failure, TIA, and foot ulceration. Further, higher age was associated with lower agreement for impaired cerebral blood flow and kidney disease, male sex with lower agreement for heart failure, and higher education with a higher agreement for angina pectoris.

Discussion
Main findings and possible explanations
To the best of our knowledge, this is the first study dealing with analysis agreement between self-reported diabetes-related comorbidities and health insurance data. We found that the agreement was high for some diabetes-related comorbidities such as MI, amputation, and hypertension; it was moderate for the comorbidities angina pectoris, stroke, peripheral neuropathy in the lower extremities, and kidney disease, and quite low for other comorbidities such as eye diseases and foot ulceration. A higher number of chronic comorbidities, long diabetes duration, and higher age were

associated with lower agreement, and higher education with higher agreement. The exceptional higher agreement for heart failure with longer diabetes duration results at least partly from combined confounding of the other factors, in particular chronic comorbidities.

High agreement was found in cases of MI, amputations, and hypertension. MI and amputations are incisive events in life, whereas patients suffering from hypertension have to cope daily with the disease because of the often-permanent need for medication. All three comorbidities have a clear, specific designation and are well known to the general public, so that differing interpretations of the questions by the study participants are not likely. This observation was found in a number of studies that analyzed agreement between self-reported and routine care data.[13]

There was a moderate degree of agreement for the comorbidities angina pectoris, stroke, peripheral neuropathy, and kidney disease. The conditions are normally manifested by a gradual process, revealing at first only little or no impairment or symptoms in everyday life. It is possible that the less specifically named diagnosis and the fact that the clinical criteria are less known to the general public might lead the study participants to assume that they are not suffering from one of these comorbidities, although this is not shown in the health insurance data, which would explain the low sensitivities for angina pectoris, neuropathy, and kidney disease.

The low sensitivity found for an apoplexy could be because of the fact that the stroke occurred over 12 months

Table 5 Odds ratios with respect to agreement from univariate and multivariate logistic regression models

Independent variables	Hypertension OR (95% CI)	Peripheral arterial disease OR (95% CI)	Angina pectoris OR (95% CI)	Myocardial infarction OR (95% CI)	Heart failure OR (95% CI)	Impaired cerebral blood flow OR (95% CI)
Unadjusted (univariate)						
Age ≥65 years	0.672 (0.403–1.120)	0.401 (0.258–0.623)	0.291 (0.180–0.470)	0.341 (0.142–0.821)	0.298 (0.171–0.519)	0.217 (0.116–0.407)
Male	0.892 (0.528–1.508)	0.911 (0.583–1.423)	0.767 (0.474–1.242)	0.308 (0.103–0.921)	0.510 (0.283–0.919)	1.263 (0.713–2.238)
Higher education	1.587 (0.934–2.696)	1.720 (1.094–2.705)	3.932 (2.276–6.793)	2.490 (0.963–6.435)	2.821 (1.547–5.143)	1.643 (0.909–2.970)
Higher income	1.154 (0.670–1.987)	1.438 (0.892–2.318)	1.196 (0.713–2.007)	1.155 (0.468–2.850)	1.685 (0.916–3.098)	0.779 (0.423–1.433)
VAS >75	1.019 (0.607–1.711)	2.597 (1.600–4.216)	1.271 (0.792–2.039)	2.162 (0.836–5.588)	1.607 (0.920–2.808)	2.565 (1.334–4.931)
No. of chronic diseases >5	0.649 (0.390–1.081)	0.230 (0.144–0.368)	0.158 (0.092–0.271)	0.151 (0.050–0.450)	0.156 (0.082–0.297)	0.231 (0.122–0.438)
Diabetes duration ≥10 years	0.804 (0.474–1.364)	0.354 (0.215–0.584)	0.358 (0.209–0.613)	0.640 (0.258–1.588)	1.191 (0.699–2.030)	0.302 (0.148–0.617)
Adjusted (multivariate)						
Age ≥65 years	0.941 (0.500–1.769)	0.917 (0.522–1.614)	0.859 (0.462–1.600)	0.743 (0.261–2.111)	0.550 (0.270–1.118)	0.363 (0.168–0.782)
Male	0.973 (0.556–1.704)	0.784 (0.467–1.317)	0.635 (0.350–1.150)	0.327 (0.105–1.019)	0.391 (0.190–0.802)	1.200 (0.623–2.312)
Higher education	1.556 (0.842–2.875)	1.205 (0.689–2.108)	2.814 (1.448–5.470)	1.958 (0.638–6.008)	1.878 (0.894–3.943)	1.141 (0.543–2.400)
Higher income	0.992 (0.557–1.767)	1.375 (0.803–2.355)	0.963 (0.529–1.753)	0.924 (0.349–2.444)	1.593 (0.798–3.181)	0.601 (0.304–1.189)
VAS >75	0.870 (0.487–1.553)	1.792 (1.023–3.139)	0.597 (0.324–1.100)	1.358 (0.459–4.019)	1.039 (0.518–2.084)	1.742 (0.815–3.727)
No. of chronic diseases >5	0.740 (0.397–1.380)	0.349 (0.198–0.613)	0.228 (0.117–0.445)	0.157 (0.041–0.606)	0.195 (0.089–0.427)	0.488 (0.228–1.049)
Diabetes duration ≥10 years	0.853 (0.474–1.534)	0.477 (0.269–0.847)	0.339 (0.171–0.671)	0.870 (0.310–2.441)	2.006 (1.021–3.943)	0.502 (0.225–1.118)

Independent variables	Stroke OR (95% CI)	Transient ischemic attack OR (95% CI)	Eye diseases OR (95% CI)	Peripheral neuropathy (leg) OR (95% CI)	Foot ulcerations OR (95% CI)	Kidney disease OR (95% CI)
Unadjusted (univariate)						
Age ≥65 years	0.280 (0.125–0.630)	0.580 (0.207–1.628)	1.209 (0.832–1.759)	0.812 (0.536–1.229)	0.466 (0.256–0.848)	0.313 (0.193–0.509)
Male	0.934 (0.431–2.027)	0.761 (0.256–2.264)	1.041 (0.714–1.517)	0.986 (0.648–1.501)	0.720 (0.384–1.350)	0.819 (0.505–1.330)
Higher education	2.809 (1.175–6.714)	2.379 (0.746–7.584)	0.961 (0.663–1.394)	1.129 (0.745–1.710)	1.673 (0.901–3.109)	1.740 (1.068–2.835)
Higher income	1.103 (0.466–2.611)	0.595 (0.196–1.801)	0.750 (0.503–1.118)	0.975 (0.626–1.518)	1.413 (0.733–2.726)	1.557 (0.921–2.631)
VAS >75	2.014 (0.873–4.648)	4.984 (1.112–22.346)	0.847 (0.583–1.231)	1.987 (1.283–3.077)	2.203 (1.135–4.277)	1.305 (0.806–2.115)
No. of chronic diseases >5	0.227 (0.095–0.542)	0.185 (0.052–0.665)	1.256 (0.867–1.820)	0.692 (0.459–1.045)	0.303 (0.160–0.574)	0.333 (0.204–0.542)
Diabetes duration ≥10 years	0.370 (0.148–0.926)	0.740 (0.249–2.202)	1.414 (0.968–2.066)	1.248 (0.824–1.890)	0.348 (0.169–0.716)	0.541 (0.326–0.898)
Adjusted (multivariate)						
Age ≥65 years	0.665 (0.244–1.815)	1.374 (0.397–4.751)	1.131 (0.703–1.819)	0.787 (0.462–1.340)	0.890 (0.426–1.858)	0.431 (0.236–0.789)
Male	0.764 (0.308–1.896)	0.641 (0.189–2.179)	1.047 (0.693–1.581)	0.989 (0.623–1.571)	0.580 (0.286–1.176)	0.785 (0.450–1.368)
Higher education	1.829 (0.640–5.226)	2.691 (0.661–10.946)	1.104 (0.709–1.718)	0.963 (0.585–1.585)	1.386 (0.657–2.927)	1.180 (0.648–2.149)
Higher income	0.830 (0.329–2.095)	0.435 (0.135–1.406)	0.738 (0.483–1.128)	0.938 (0.583–1.509)	1.225 (0.604–2.485)	1.454 (0.816–2.589)
VAS >75	1.790 (0.620–5.165)	2.601 (0.541–12.504)	0.938 (0.612–1.438)	1.819 (1.109–2.986)	1.608 (0.754–3.429)	0.862 (0.486–1.528)
No. of chronic diseases >5	0.435 (0.151–1.257)	0.172 (0.033–0.891)	1.102 (0.693–1.753)	0.911 (0.543–1.528)	0.384 (0.178–0.828)	0.563 (0.308–1.030)
Diabetes duration ≥10 years	0.417 (0.133–1.304)	0.875 (0.248–3.093)	1.235 (0.808–1.889)	1.435 (0.892–2.308)	0.526 (0.242–1.140)	0.754 (0.418–1.361)

Notes: Patients with missing values excluded from analyses (univariate models; multivariate models: 59 patients excluded).
Abbreviations: OR, odds ratio; VAS, visual analog scale.

before (the period in question), but that the occurrence was still to be found in the health insurance data.[26]

The possibility of ambiguous interpretation, unknown clinical criteria, and an asymptomatic progression of the disease, which often shows itself later, may all have contributed to the numerous disagreeing data for the comorbidity of heart failure.

With regard to eye diseases, there was low agreement between the self-reported data and the data from the SHIs. Patients with diabetes are recommended to have their eyes examined regularly.[27] It may be assumed that the eye specialist will make a series of diagnoses that seem to be less illness-relevant for the patient and remain therefore unmentioned by him or her.

The agreement between the self-reported data on foot ulcerations (badly healing ulcers, infections, or wounds on the feet) and the data from the SHIs can be described only as "satisfactory". Here it is difficult to find a suitable explanation. It is difficult to describe diabetic foot ulceration for the patients, and, in particular, there is no specific ICD code.

The lowest agreement (corresponding to kappa) between the self-reported data and that from the SHIs was found for impaired cerebral blood flow, TIAs, and eye diseases. Here only a few of the self-reported data could be confirmed by the secondary data and vice versa. The study participants were probably unfamiliar with the definition of a TIA, and diagnoses of TIAs received the ICD code for apoplexy in the secondary data. However, the case numbers were low (n=7).

Regarding factors that may affect agreement, a higher number of comorbidities was particularly associated with lower agreement. Further, a higher age and male sex were associated with lower agreement, whereas agreement was higher in more highly educated patients. A lower agreement with higher age and a higher number of comorbidities has been found in several other studies.[13–15,28–32]

Limitations and strengths
Limitations
Several limitations have to be considered: 1) This study is based on data collected from patients from a single practice specializing in diabetes, and from one single SHI. Patients from specialized practices are more likely to have an unfavorable progression of their illness, which requires specialized treatment. For this reason the results cannot be applied to the whole diabetic population. 2) As is common to other studies, the health insurance data regarding the diagnosis of an individual participant are defined as "closer to the truth" when compared with the self-reported data provided by the same participant. Thus, the individual data concerning sensitivity,

specificity, NPVs, and PPVs of a comorbidity were calculated according to the health insurance data. However, the health insurance data are also susceptible to errors, not least because the financial compensation for the physicians depends greatly on the diagnoses billed. 3) Another of this study's limitations is the lack of a standardized translation of the self-reported data into ICD codes. However, the translation of the comorbidities into ICD codes was checked according to the dual-control principle with the assistance of a physician who was familiar with the method. However, a certain amount of subjectivity could not be ruled out. For some of the comorbidities, for example impaired cerebral blood flow, it remains questionable as to how far they can be translated into ICD codes corresponding to those used by physicians. 4) Some events like amputation or MI may have occurred >12 months before and yet still be documented in the SHI data. In this case, the patient's self-report would be correct. This could explain the low sensitivity for MI in our data. 5) In some comorbidities, only a few cases were observed, which implies imprecise estimates and low power in regression analyses (in particular for TIA, amputations, and dialysis). In these cases descriptive results should be in the primary focus, and estimates from multiple regression (Table 5) should be interpreted with great caution. 6) Finally, we restricted the regression analyses to one outcome to obtain a manageable number of results. We chose "agreement" because a main focus was to investigate the use of self-reports for epidemiologic studies. Furthermore, "agreement" was often used in other publications.[12,13]

Strengths
1) When making the self-report in the questionnaire, the study participant was always able to call on one of the study assistants for help, if necessary. This means that a positive influence on the correctness and completeness of the statements made by a study participant can be expected. 2) In contrast to other studies, patients who had not reported comorbidities were also included in the analysis, reducing bias from underreporting. 3) Finally, the SHI data were subjected to detailed plausibility and completeness checks. Altogether, high data quality can be assumed.

Implications of the study findings and conclusions
Our study has important implications. First, patients' awareness of their own diabetes-related comorbidities, which is urgently needed for effective self-management, seems to be limited. Patients with diabetes have a substantial need for information, but a large proportion of patients with diabetes have stated that they are not well informed about the disease.[10,11] Hence,

more effort should be made to provide diabetic patients with effective information. Second, when we use self-reported data to adjust for comorbidity in observational studies, we have to take into consideration that the validity of the data is limited.

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Disclosure

The authors report no conflicts of interest in this work.

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Supplementary material
Original question and comorbidities in the patient questionnaire

Please indicate which of these diseases you have or have had in the past 12 months. These are the medical conditions that your doctor has identified with you.

Hypertension (high blood pressure); peripheral arterial occlusive disease (nicknamed "window-shopping disease" in German: pain in the legs or calves while walking, which is why one must stop walking for the pain to subside); circulatory disorders of the heart (angina pectoris); heart attack; heart failure (cardiac insufficiency); blood circulation disorder of the brain; stroke; transient ischemic attack (transient bleeding disorder of the brain with stroke-like symptoms); disorders of the eyes (e.g., eye damage, cataract); disorders of the nerves in the legs (e.g., burning, tingling, or numbness); inflammations, ulcers, or wounds on the feet that are healing badly; amputation of feet/legs; disorders of the kidney (e.g., excretion of protein in the urine); dialysis-compulsory (blood-cleansing); cancer disease (malignant tumor); thyroid disease; gout; chronic (persistent) back pain; inflammatory articular or spinal disease (e.g., arthritis); other joint or spinal disorders; stomach or duodenal ulcer or chronic gastric mucosa inflammation; inflammatory disease (e.g., ulcerative colitis, Crohn's disease); other indications; gallstones; common urinary tract infections (bladder infections); chronic liver inflammation (hepatitis); allergy(s), hay fever; bronchial asthma; chronic bronchitis or chronic obstructive pulmonary disease; anaemia; chronic skin diseases (e.g., neurodermatitis, psoriasis); migraine; epilepsy; Parkinson's disease; depression.