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# Cross-sectional analysis of adult diabetes type 1 and type 2 patients with diabetic microvascular complications from a German retrospective observational study

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*Key words:* Diabetes – Type 1 – Type 2 – Microvascular complications – Prevalence

## ABSTRACT

*Objective:* To obtain epidemiological data on the prevalence of predefined stages of diabetic microvascular complications from a representative cross-section of patients with existing microvascular complications of type 1 or type 2 diabetes in Germany.

*Research design and methods:* A cross-sectional, retrospective study of medical records of 705 type 1 and 1910 type 2 adult diabetic patients with a diagnosis of retinopathy and/or peripheral neuropathy and/or nephropathy before 2002 and treated in 2002 in Germany.

*Results:* Of 376 patients with type 1 diabetes having retinopathy, 59.3% had mild or moderate non-proliferative retinopathy without macular oedema, 27.1% had macular oedema, and 13.6% had severe retinopathy without macular oedema. In 862 patients with type 2 diabetes, the distribution of retinopathy/maculopathy classes was 56.8%, 35.5%, and 7.7%, respectively.

Of 381 type 1 diabetes patients with observed peripheral neuropathy, 81.4% had sensorimotor neuropathy, 8.9% had diabetic foot conditions, and 9.7% had lower extremity amputations because of diabetes. In 1005 patients with type 2 diabetes, the distribution of neuropathy classes was 78.2%, 12.1%, and 9.7%, respectively. The proportions of patients with renal insufficiency in type 1 and type 2 diabetes groups were 15.3% versus 13.5%, respectively.

*Conclusions:* The study suggests that there are considerable proportions of patients with progressive stages of microvascular complications related to type 1 and type 2 diabetes in Germany. This underlines the importance of improvement of optimal quality of care and frequent screening for preventing late diabetic microvascular complications and the necessity of effective intervention strategies to tackle this major public health problem.

## Introduction

Diabetes mellitus (DM) is a metabolic disorder characterized by hyperglycaemia and disturbances of protein, fat and carbohydrate metabolism, which results from impaired insulin secretion, insulin action or both<sup>1</sup>. The microvascular complications of diabetes affect small blood vessels<sup>2</sup>. Long-term microvascular complications of diabetes include: retinopathy, which may lead to blindness; neuropathy, which increases the risk of foot ulcers and amputations; and nephropathy with potential renal failure<sup>1</sup>.

According to the World Health Organization (WHO) estimates, about 171 million people aged 20 years or more worldwide had diabetes in the year 2000<sup>3</sup>. The prevalence of diabetes in Germany for the year 2000 was estimated by WHO to be about 2.6 million<sup>4</sup>. According to AOK, the largest statutory health insurance in Germany, there was a continuous increase in the prevalence of diagnosed DM from 6.0% in 1998 to 6.9% in 2001<sup>5</sup>. Increase in prevalence of diabetes generally results from population aging<sup>3</sup>, reduced physical activity and increased obesity<sup>3</sup>, and high caloric intake<sup>6</sup>. It is estimated that 10% of all patients with diabetes have the type 1 variety<sup>7</sup>. An estimated 22.9%<sup>8</sup> of adult Germans are obese (body mass index [BMI]  $\geq 30$ ) and about half of all adults are overweight<sup>9</sup>. The growing prevalence of an elderly population, of people with excess body fat and being physically inactive will contribute to an increasing prevalence of type 2 diabetes in Germany.

According to the KORA-Survey 2000, about half of the total cases with diabetes in southern Germany are underdiagnosed<sup>10</sup>. A study on diabetes prevalence among patients scheduled for a coronary angiography has shown that about half of the patients with diabetes were previously undiagnosed<sup>11</sup>. Numerous studies regarding the prevalence of diabetes have been conducted in Germany. Most of the data available concerning the prevalence of diabetes and its complications in Germany have been derived from selected populations, e.g. the MONICA/KORA Surveys for Southern Germany<sup>10</sup>, a population-based study based on a random sample of all members of AOK in Hesse<sup>5</sup>, and the JEVIN Trial of diabetes patients living in the city of Jena<sup>12,13</sup>. The hypertension and diabetes screening and awareness (HYDRA) study provided data on the prevalence of diabetes among a nationally representative sample of primary care patients in Germany<sup>14</sup>.

According to the Diabetes Control and Complications Trial<sup>15</sup> and the United Kingdom Prospective Diabetes Study<sup>16</sup>, chronic hyperglycaemia is associated with an increased incidence of developing the microvascular complications of diabetes. In Germany, data on the management of the microvascular complications

are often not properly recorded and thus not easily extracted from medical records.

As of today, epidemiological data on prevalence of stages of microvascular complications in patients with existing microvascular complications of type 1 or type 2 DM in Germany is sparse. Such information on the epidemiology of diabetes and its complications is, however, required in order to make reliable estimates and projections of the economic burden associated with diabetes and its complications which, in turn, are necessary to carefully plan and appropriately allocate public health resources.

This study collected data from specialists treating diabetic microvascular complications in order to evaluate the prevalence of certain predefined stages of diabetic retinopathy, neuropathy and nephropathy.

## Patients and methods

This non-interventional, retrospective, observational study was carried out in Germany in 2003. The objective was to determine the frequency distribution of predefined stages of diabetic microvascular complications among type 1 or type 2 DM patients in whom at least one of the three principal sequelae associated with diabetes (retinopathy, peripheral neuropathy and nephropathy) was present. One hundred and fourteen physicians have participated in the epidemiological part of the study. Physicians were randomly selected from a German physicians' database, including more than 155 000 physicians<sup>17</sup>. General practitioners (GP), diabetologists and ophthalmologists were separately selected from the database, which was modified to contain only these medical specialities. Data from the medical records of patients with diabetes seen in general practice in 2002 were collected. Selection of medical records for this study was achieved by reviewing paper charts of all patients in each practice sorted in alphabetical order, starting from randomly chosen letters from the 26-letter German alphabet which were provided to physicians. Data documentation was done anonymously in order to comply with the data protection law. This study follows the German ethics rules (according to the Declaration of Helsinki 1996). Each physician documented the requested data from the records of consecutive patients with at least one microvascular complication related to diabetes, aged at least 18 years, who were still receiving treatment in the year 2002. Physicians recorded the following patient-related variables: age, gender, smoking status, BMI, hypertension, diabetes diagnosis date, glycosylated haemoglobin (HbA<sub>1c</sub>) and microvascular complications. For BMI, smoking status, hypertension, HbA<sub>1c</sub> and microvascular complications, the most recent value or information noted was used. Each physician

was supposed to document 20 patients. It was originally planned that each physician would document an equal proportion of patients with type 1 and type 2 DM; however, patients with type 2 DM were twice as likely to be documented by each physician's category as those with type 1 DM. In total, data for 2615 diabetic patients have been documented by 45 ophthalmologists, 36

general practitioners and 33 diabetologists (Table 1). All documented patients had at least one of the following microvascular complications: diabetic retinopathy, alone or in combination with macular oedema (ME), and/or peripheral neuropathy and/or nephropathy. Of these patients, 705 (27%) had a type 1 and 1910 (73%) type 2 DM (Table 2).

**Table 1.** The number of diabetic patients documented by physicians in our study

Physicians	Patients with diabetes type 1 ( <i>n</i> = 705)	Patients with diabetes type 2 ( <i>n</i> = 1910)	Total number of patients ( <i>n</i> = 2615)
45 ophthalmologists			
<i>n</i> (%)	272 (39%)	706 (37%)	978 (37%)
Mean ± SD	6 ± 3	16 ± 5	22 ± 4
Median (range)	6 (0–10)	15 (8–30)	20 (9–30)
36 general practitioners			
<i>n</i> (%)	187 (27%)	627 (33%)	814 (31%)
Mean ± SD	5 ± 4	18 ± 5	23 ± 6
Median (range)	6 (0–10)	19 (10–32)	20 (11–38)
33 diabetologists			
<i>n</i> (%)	246 (35%)	577 (30%)	823 (31%)
Mean ± SD	7 ± 4	17 ± 5	25 ± 5
Median (range)	10 (0–11)	20 (9–29)	25 (14–30)

SD = standard deviation, *n* = number of patients

**Table 2.** Patients' characteristics

Characteristic	Diabetes type 1 ( <i>n</i> = 705)	Diabetes type 2 ( <i>n</i> = 1910)	Total ( <i>n</i> = 2615)
Age, years, mean ± SD (range)	52 ± 15 (18–90)	68 ± 10 (32–95)	64 ± 14 (18–95)
Gender, % (male/female/unknown)	55/44/1	49/49/1	51/48/1
BMI, kg/m <sup>2</sup> , mean ± SD	26 ± 4	29 ± 5	28 ± 5
Smoking status, %, current/ex-smoker/never/unknown	17/14/54/15	11/18/55/16	13/17/55/15
Time since diagnosis, years, mean ± SD	21 ± 12	13 ± 8	15 ± 10
Hypertension, %	45	71	64
HbA <sub>1c</sub> , %, mean ± SD	7.4 ± 1.3	7.3 ± 1.3	7.3 ± 1.3
Retinopathy, <i>n</i> (%)			
Yes	443 (63)	969 (51)	1412 (54)
No	171 (24)	569 (30)	740 (28)
Unknown	91 (13)	372 (19)	463 (18)
Neuropathy, <i>n</i> (%)			
Yes	408 (58)	1072 (56)	1480 (57)
No	128 (18)	333 (17)	461 (18)
Unknown	169 (24)	505 (26)	674 (26)
Nephropathy, <i>n</i> (%)			
Yes	315 (45)	872 (46)	1187 (45)
No	212 (30)	515 (27)	727 (28)
Unknown	178 (25)	523 (27)	701 (27)

Percentages may not sum to 100% because of rounding

SD = standard deviation, BMI = body mass index, *n* = number of patients

## Classification of stages

### Retinopathy

The assessment of retinopathy was done on the basis of direct ophthalmoscopy (funduscopy) through a dilated pupil by an ophthalmologist, as documented in patients' records. Severity classes of retinopathy were based on the 'International Clinical Classification for Diabetic Retinopathy', suggested in 2002<sup>18</sup>. This classification was modified for this study to include ME as an additional class: Class 1, mild non-proliferative retinopathy without ME (micro-aneurysms only); Class 2, moderate non-proliferative retinopathy without ME (more than mild but less than severe); Class 3, severe non-proliferative retinopathy without ME (20 or more intraretinal haemorrhages in four quadrants, and/or definite venous beading in two or more quadrants, and/or prominent intraretinal microvascular abnormalities in one or more quadrants); Class 4, proliferative retinopathy without ME (definite neovascularization and/or preretinal/vitreous haemorrhage); and Class 5, ME with or without proliferative or non-proliferative retinal abnormalities. Patients with retinopathy, alone or in combination with ME, will hereafter be referred to as 'retinopathy' patients.

### Peripheral neuropathy

Diagnosis of peripheral neuropathy was made by judgment of a physician and was based on prior history of lower extremity amputation, results of clinical examination (ankle tendon reflexes, temperature sensation, and vibration perception test with a 128 Hz tuning fork) and symptoms such as pain or paraesthesia. The classification of peripheral neuropathy stages was based on the following findings: Stage 1 (subclinical sensorimotor neuropathy), Stage 2 (symptomatic sensorimotor neuropathy), Stage 3 (diabetic foot conditions, such as, foot deformations, ulcers, etc.), Stage 4 (lower extremity amputation because of diabetes in 2002) and Stage 5 (lower extremity amputation because of diabetes before 2002).

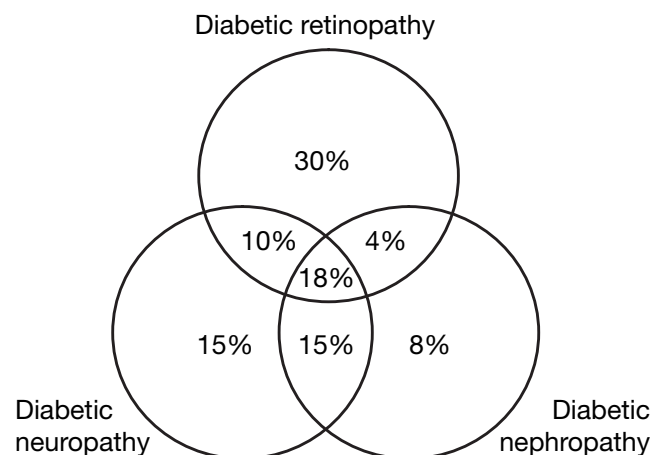
### Nephropathy

Nephropathy was assessed based on the clinical signs of diabetic damage to the kidneys: microalbuminuria, macroalbuminuria, and renal failure according to the guidelines of the German Diabetes Association<sup>19</sup>. Urinary albumin, urinary creatinine, creatinine clearance and HbA<sub>1c</sub> were measured using conventional methods.

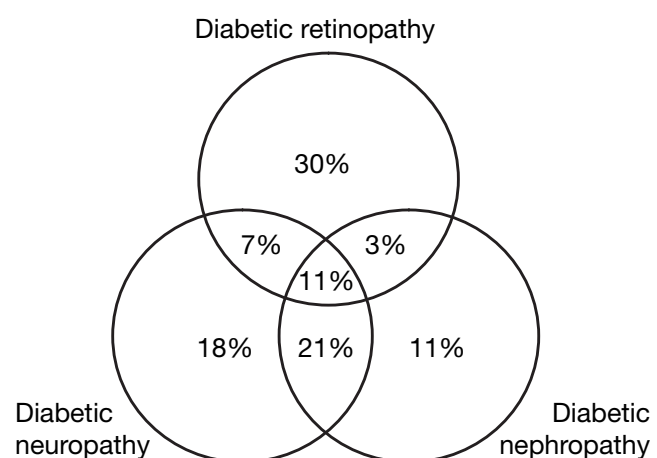
Descriptive analyses were performed using SAS Software (version 8.2; SAS Institute Inc., Cary, NC, USA).

## Results

The patients with type 1 DM were younger than those having type 2 DM (52 vs. 68 years, respectively), as shown in Table 2. The patients had diabetes for an average of 15 years. The mean HbA<sub>1c</sub> levels did not differ between type 1 and type 2 diabetic patients. Venn diagrams showing proportions of patients with different microvascular complications among type 1 and type 2 DM patients are shown in Figures 1 and 2. In type 1 DM patients with retinopathy ( $n = 443$ ), 48% (214) had retinopathy only, 6% (28) had retinopathy and nephropathy, 16% (72) had retinopathy and peripheral neuropathy and 29% (129) had all three microvascular complications. In type 2 DM patients with retinopathy ( $n = 969$ ), 59% (574) had retinopathy only, 6% (54) had retinopathy and nephropathy, 13%



**Figure 1.** Proportions of patients with different microvascular complications among type 1 diabetes patients in this study



**Figure 2.** Proportions of patients with different microvascular complications among type 2 diabetes patients in this study

(126) had retinopathy and peripheral neuropathy and 22% (215) had all three microvascular complications.

In 1238 of 1412 (87.7%) of the patients in whom a retinopathy had been reported, information on retinopathy severity grade was available and the distribution of retinopathy stages with or without ME in patients

with type 1 and type 2 diabetes is shown in Tables 3 and 4. Approximately 13% of type 1 DM patients with documented retinopathy severity grade had severe non-proliferative diabetic retinopathy (SNPDR) vs. 18.3% of type 2 DM patients, and 17% of type 1 DM patients had proliferative diabetic retinopathy (PDR)

**Table 3.** Macular oedema in patients with diabetic retinopathy

Status of retinopathy/macular oedema	Diabetes type 1 (n = 376*/443†)	Diabetes type 2 (n = 862*/969†)	Total (n = 1238*/1412†)
Mild NPDR without ME, n (%)	149 (39.6%)	315 (36.5%)	464 (37.5%)
Mild NPDR with ME, n (%)	8 (2.1%)	29 (3.4%)	37 (3.0%)
CSME, n (%)	4 (1.1%)	15 (1.7%)	19 (1.5%)
CIME, n (%)	4 (1.1%)	13 (1.5%)	17 (1.4%)
ME, status unknown, n (%)	–	1 (0.1%)	1 (0.1%)
Moderate NPDR without ME, n (%)	74 (19.7%)	175 (20.3%)	249 (20.1%)
Moderate NPDR with ME, n (%)	32 (8.5%)	95 (11.0%)	127 (10.3%)
CSME, n (%)	18 (4.8%)	71 (8.2%)	89 (7.2%)
CIME, n (%)	12 (3.2%)	23 (2.7%)	35 (2.8%)
ME, status unknown, n (%)	2 (0.5%)	1 (0.1%)	3 (0.2%)
SNPDR without ME, n (%)	20 (5.3%)	41 (4.8%)	61 (4.9%)
SNPDR with ME, n (%)	29 (7.7%)	116 (13.5%)	145 (11.7%)
CSME, n (%)	22 (5.9%)	103 (12.0%)	125 (10.1%)
CIME, n (%)	6 (1.6%)	10 (1.2%)	16 (1.3%)
ME, status unknown, n (%)	1 (0.3%)	3 (0.4%)	4 (0.3%)
PDR without ME, n (%)	31 (8.2%)	25 (2.9%)	56 (4.5%)
PDR with ME, n (%)	33 (8.8%)	66 (7.7%)	99 (8.0%)
CSME, n (%)	27 (7.2%)	62 (7.2%)	89 (7.2%)
CIME, n (%)	6 (1.6%)	4 (0.5%)	10 (0.8%)

Percentages may not sum to 100% because of rounding

NPDR = non-proliferative diabetic retinopathy, SNPDR = severe non-proliferative diabetic retinopathy, PDR = proliferative diabetic retinopathy, CSME = clinically significant macular oedema, CIME = clinically insignificant macular oedema, ME = macular oedema

\*Patients with available data on retinopathy severity class

†Total number of patients with retinopathy

**Table 4.** Distribution of retinopathy severity classes in patients with type 1 and type 2 diabetes according to a modified classification of retinopathy

Retinopathy severity class	Diabetes type 1 (n = 376*/443†)	Diabetes type 2 (n = 862*/969†)	Total (n = 1238*/1412†)
Mild NPDR without ME, n (%)	149 (39.6%)	315 (36.5%)	464 (37.5%)
Moderate NPDR without ME, n (%)	74 (19.7%)	175 (20.3%)	249 (20.1%)
SNPDR without ME, n (%)	20 (5.3%)	41 (4.8%)	61 (4.9%)
PDR without ME, n (%)	31 (8.2%)	25 (2.9%)	56 (4.5%)
ME with or without other abnormalities, n (%)	102 (27.1%)	306 (35.5%)	408 (33.0%)

Percentages may not sum to 100% because of rounding

NPDR = non-proliferative diabetic retinopathy, SNPDR = severe non-proliferative diabetic retinopathy, PDR = proliferative diabetic retinopathy, ME = macular oedema

\*Patients with available data on retinopathy severity class

†Total number of patients with retinopathy

**Table 5.** Distribution of peripheral neuropathy classes in patients with type 1 and type 2 diabetes

Peripheral neuropathy class	Diabetes type 1 (n = 381*/408†)	Diabetes type 2 (n = 1005*/1072†)	Total (n = 1386*/1480†)
Subclinical sensorimotor neuropathy, n (%)	134 (35.2%)	315 (31.3%)	449 (32.4%)
Symptomatic sensorimotor neuropathy, n (%)	176 (46.2%)	471 (46.9%)	647 (46.7%)
Diabetic foot conditions such as foot deformations, ulcers, etc., n (%)	34 (8.9%)	122 (12.1%)	156 (11.3%)
Lower extremity amputation because of diabetes in 2002, n (%)	16 (4.2%)	37 (3.7%)	53 (3.8%)
Lower extremity amputation because of diabetes before 2002, n (%)	21 (5.5%)	60 (6.0%)	81 (5.8%)

Percentages may not sum to 100% because of rounding

\*Patients with available data on peripheral neuropathy class

†Total number of patients with peripheral neuropathy

**Table 6.** Distribution of nephropathy severity classes in patients with type 1 and type 2 diabetes

Nephropathy severity class	Diabetes type 1 (n = 294*/315†)	Diabetes type 2 (n = 838*/872†)	Total (n = 1132*/1187†)
Microalbuminuria, n (%)	202 (68.7%)	514 (61.3%)	716 (63.3%)
Macroalbuminuria, n (%)	47 (16.0%)	211 (25.2%)	258 (22.8%)
Renal insufficiency, n (%)	45 (15.3%)	113 (13.5%)	158 (14.0%)

Percentages may not sum to 100% because of rounding

\*Patients with available data on nephropathy severity class

†Total number of patients with nephropathy

compared to 11% of type 2 DM patients. Prevalence of clinically significant macular oedema (CSME) among patients with available information on retinopathy severity class was 18.9% (71 of 376 type 1) and 29.1% (251 of 862 type 2 DM patients). Of 376 type 1 DM patients having retinopathy with or without ME, 59.3% had mild or moderate non-proliferative retinopathy (NPDR) without ME, 27.1% had ME and 13.6% had SNPDR or PDR without ME (vs. 56.8%, 35.5% and 7.7% for type 2 DM, respectively).

In 1386 of 1480 (93.6%) of the patients in whom peripheral neuropathy had been reported, information on neuropathy severity class was available (Table 5). Distribution of peripheral neuropathy severity classes did not differ between type 1 and type 2 DM. Of 381 type 1 DM patients with observed peripheral neuropathy, 81.4% had sensorimotor neuropathy, 8.9% had diabetic foot conditions and 9.7% had lower extremity amputation because of diabetes. The distribution of neuropathy classes in 1005 patients with type 2 DM was 78.2%, 12.1% and 9.7%, respectively.

In 1132 of 1187 (95.4%) of the patients in whom nephropathy had been reported, information on nephropathy severity class was available (see Table 6). The proportion of patients with renal insufficiency in patients with type 1 was similar to that in the type 2 diabetes group, but the prevalence of macroalbuminuria was higher among patients with type 2 diabetes.

## Discussion

Until 1989, all diabetic patients in the former East Germany were registered under a centralized diabetes care system<sup>20,21</sup>. In West Germany there was no such system for health care of diabetic patients. In the early 1990s, specialised diabetology was performed exclusively in hospitals<sup>22</sup>. Within a few years, physicians practising in offices in most regions of Germany were granted permission of ambulatory management of diabetes patients<sup>22</sup>. Since 1998, annual examinations of diabetes patients for preventive purposes and documentation of microvascular complications are implemented by physicians<sup>22</sup>. Most patients in Germany are now treated by general practitioners and about one fifth of DM patients by diabetologists<sup>23</sup>. Based on the rationale that an accurate estimation of the prevalence of stages of microvascular complications can be assessed only by using reliable sources for identification of diabetic patients having at least one microvascular complication, one of the most comprehensive physicians' databases for Germany was used in this study.

This is a cross-sectional, epidemiological study with a retrospective component in a nationally representative sample of physicians that was designed to assess the frequency distribution of severity stages of retinopathy, alone or with ME, peripheral neuropathy, and

nephropathy in patients with diabetes. Data from the medical records of diabetic patients who routinely visited their physicians were collected.

On average, patients in both diabetes groups had acceptable metabolic control according to the mean HbA<sub>1c</sub>; similar results were reported by the KORA Survey 2000<sup>24</sup>. An average duration of disease in patients with type 1 DM was much longer when compared to patients with type 2 DM. About one in three diabetic patients with documented data on retinopathy severity class had severe NPDR or PDR. The proportion of patients having CSME in patients with documented retinopathy severity grade was about 1.5-fold higher in patients with type 2 diabetes.

In this study, the proportion of patients having foot ulcers, other diabetic foot conditions or lower extremity amputation was similar between the two diabetes groups. One fifth of patients with existing peripheral neuropathy conditions had a diabetic foot condition or lower extremity amputation because of diabetes, and about one tenth of patients with varying degrees of renal impairment related to diabetes suffered from renal insufficiency.

While interpreting the data, the likelihood of under-reporting, over-reporting or selection bias must be taken into account. Patients in the study sample had at least one diabetic microvascular complication, which means that patients without such complications were not a part of our study. The ophthalmologists were separately selected from the physicians' database for this study; all patients with diabetes in Germany visit them on a yearly basis. Equal proportions of diabetologists and GPs were selected. The high proportion of diabetologists in our sample might lead to over-representation of progressive stages, if we assume that patients with more severe complications are referred to diabetologists. On the other hand, a patient with diabetes regardless of disease severity might prefer being managed by a diabetologist rather than by a GP, so he may ask his GP about referral to a diabetologist. If we assume that diabetologists probably better manage diabetes than general practitioners, then with time progression of diabetes in patients at diabetologists will be slowed down, leading to a significantly lower proportion of patients with severe diabetic complications than among diabetic patients treated by GPs only. We do not think, however, that selection of equal numbers of GPs and diabetologists might have led to over-representation of patients with severe complications in our study sample. In fact, the proportion of nephropathy severity stages among all patients with type 1 DM reported by GPs did not differ from that reported by diabetologists for the relevant patient category ( $p = 0.1949$ , by Chi-square test); similar findings for testing the differences in

distribution of nephropathy severity classes among type 2 DM between these two physician groups were noted ( $p = 0.1160$ , by Chi-square test).

The results obtained from this study are not easily comparable to those from other studies with different methodologies. Caution needs to be taken in generalising the results to the whole diabetes population.

## Conclusion

This study suggests that there are considerable proportions of patients with progressive stages of the microvascular complications related to type 1 or type 2 DM in Germany. There is also a need for improvement in documentation of patient medical records. Severe microvascular complications are not uncommon, although metabolic control seems to be acceptable in a majority of diabetic patients in whom at least one microvascular complication was diagnosed. This underlines the importance of improvement of optimal quality of care for preventing and treating late microvascular complications, frequent screening for timely diagnosis of disease progression in diabetic patients, adequate medical documentation, and the necessity of effective intervention strategies in order to tackle this major public health problem.

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