Older Subjects With Diabetes and Prediabetes Are Frequently Unaware of Having Distal Sensorimotor Polyneuropathy

The KORA F4 Study

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OBJECTIVE—Distal sensorimotor polyneuropathy (DSPN) is a severe complication of type 2 diabetes. This study aimed to assess the prevalence of unawareness of DSPN in prediabetes and diabetes in a sample of the older population of Augsburg, Germany.

RESEARCH DESIGN AND METHODS—Glucose tolerance status was determined in 61- to 82-year-old participants of the population-based KORA F4 Study (2006–2008) (n = 1,100). Clinical DSPN was defined as the presence of bilaterally impaired foot-vibration perception and/or bilaterally impaired foot-pressure sensation. DSPN case subjects were considered unaware of their condition when answering "no" to the question, "Has a physician ever told you that you are suffering from nerve damage, neuropathy, polyneuropathy, or diabetic foot?"

RESULTS—Clinical DSPN was prevalent in 154 (14%) participants, 140 of whom were unaware of their disorder. At a prevalence of 23.9% (95% CI 12.6–38.8), participants with combined impaired fasting glucose and impaired glucose tolerance had the highest prevalence of DSPN. Of these, 10 of 11 (91%) were unaware of having clinical DSPN. Participants with known diabetes had an equally high prevalence of DSPN [22.0% (16.2–28.9)], with 30 of the 39 (77%) DSPN case subjects unaware of having the disorder. Among subjects with known diabetes who reported to have had their feet examined by a physician, 18 of 25 (72%) clinical DSPN case subjects emerged unaware of having DSPN.

CONCLUSIONS—Our findings showed a high prevalence of unawareness of having clinical DSPN among the prediabetic and diabetic groups and an insufficient frequency of professional foot examinations, suggesting inadequate attention to diabetic foot prevention practice.

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iabetic peripheral neuropathy is a severe complication of type 2 diabetes related to chronic hyperglycemia and the presence of cardiovascular risk factors (1). Symmetrical distal sensorimotor polyneuropathy (DSPN), the most common form of peripheral

neuropathies in patients with diabetes, is a heterogeneous disorder covering a wide range of abnormalities that affect peripheral sensory and motor nerves as well as the autonomic nervous system (2). Of all diabetes complications, DSPN is responsible for the highest number of

hospital admissions and, being the foremost cause of foot ulcers, for 50–75% of all nontraumatic amputations after ulceration (3). Next to substantial morbidity, DSPN leads to reduced quality of life and an increased risk of mortality (1,4).

In recognition of the importance of early detection and prevention of DSPN, American (5), British (6), and German (7) national guidelines for diabetes care state that all patients with type 2 diabetes should be screened for clinical DSPN at the time of their diabetes diagnosis and yearly thereafter. Screening is to be performed using simple clinical tests, such as vibration perception, pressure sensation, assessment of ankle reflexes, and pinprick sensation. Still, several reports have indicated that in primary care practice, where most of the diabetic patients are being treated, screening for polyneuropathy was underused (8–11). Neurologic tests and physical examination of the feet are being carried out rarely in asymptomatic diabetic patients, and neuropathic pain often remains unrecognized and untreated (12). To date, there are only sparse data on the prevalence of undiagnosed DSPN (13,14). Although the two studies differed in methodology, both observed that over one-half of their study sample of diabetic patients had undiagnosed DSPN. The aim of the current study was to examine the prevalence of unawareness of having clinical DSPN among older prediabetic and diabetic individuals from a population-based sample in Germany.

RESEARCH DESIGN AND METHODS—The Cooperative Health Research in the Region of Augsburg

Research in the Region of Augsburg (KORA) was initiated to study the prevalence and incidence of various chronic diseases in the general population, including diabetes, and to identify novel risk factors of these diseases. The current study is based on the follow-up examination of the KORA S4 Survey that was conducted in 1999–2001. The study

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design and subject enrollment have previously been described in detail (15). Briefly, 2,656 men and women aged 55–74 years were randomly selected from the region of Augsburg in the south of Germany to participate in the KORA S4 Survey. From the 2,564 eligible subjects, 1,653 (64%) completed the survey and a subsequent 1,353 subjects without known diabetes successfully completed an oral glucose tolerance test (OGTT). In 2006-2008, the 7-year follow-up examination (F4 Survey) of this cohort took place, including a second OGTT. Of the initial 1,353 subjects, a total of 1,209 (89%) participated in the followup measurements. For 177 participants, a previous diagnosis of diabetes could be validated, and a further 923 participants successfully completed the OGTT, resulting in a total sample size of 1,100 (81%) subjects. All participants gave written informed consent, and the study was approved by the ethics committee of the Bavarian Medical Association.

Measurements and interviews

Height, weight, waist circumference, and systolic and diastolic blood pressure were measured according to standard protocols as previously described (15). Trained medical interviewers collected information on medical history, physical activity, smoking behavior, and alcohol consumption. Furthermore, participants with known diabetes were asked the question. "When has a physician examined your feet lately?" which could be answered with 1) within the past 12 months, 2) >12 months ago, 3) not ever, and 4) I don't know. As an indication for ever having had one's feet examined, answers 1 and 2 were considered confirmative of a foot examination and answer 3 was considered nonconfirmative.

Patients with known diabetes completed an additional self-administered questionnaire on diabetes care, which inquired about the presence of complications, the course of treatment, and whether the subject had been enrolled in a type 2 diabetes disease-management program (DDMP). Since DDMP names vary considerably between the supplying social health insurance companies and might not reveal the disease-management aspect, the family physician of each participant with known diabetes was contacted to validate DDMP participation.

Assessment of glucose metabolism

Cases of self-reported diabetes, as well as the date of diagnosis, were validated through contacting the participants' general practitioners. All other participants underwent an OGTT (World Health Organization criteria). After an overnight fasting period of at least 10 h, fasting blood samples were taken and participants were given an oral dose of 75 g anhydrous glucose (Dextro OGT; Boehringer Mannheim, Mannheim, Germany). Another blood sample was collected 2 h after the glucose load. Blood samples were collected without stasis. After withdrawal, the samples were centrifuged and refrigerated at 4°C until analysis in the central laboratory of the Augsburg Central Hospital at maximum 4 h after withdrawal. Blood glucose levels were assessed using the hexokinase method (Glu-Flex; Dade Behring, Marburg, Germany). Glucose tolerance categories were defined according to the 1999 World Health Organization diagnostic criteria (16). We considered participants with isolated impaired fasting glucose (IFG), isolated impaired glucose tolerance (IGT), or combined IFG-IGT as subjects with prediabetes. Furthermore, overall diabetes was defined as the combined group of subjects with known and newly diagnosed diabetes. It can be assumed that the great majority of case subjects with newly diagnosed diabetes in this age-group had type 2 diabetes.

Neurologic assessment

The neurologic examination of the F4 survey consisted of two parts. The first involved a detailed interview addressing the presence of (current) pain in the feet and other parts of the body, the presence of neurologic diseases, and the participant's history of foot ulcers and amputations. The second part comprised a foot inspection and a series of neurologic tests involving sensation to touch, vibration, and temperature and testing of ankle reflexes and sudomotor function.

We defined the presence of clinical DSPN as bilateral impairment of foot-vibration perception and/or bilateral impairment of foot-pressure sensation. Vibration perception was assessed at the dorsal side of the left and right big toe, using a calibrated 64-Hz Rydel Seiffer tuning fork. Increased thresholds were calculated according to the study of Martina et al. (17). Pressure sensation was measured at the dorsal side of the left and right big toe in between the nail fold and the metatarsophalangeal joint, using a 10-g monofilament (Twin-Tip, Heinsberg, Germany). Participants were

asked to close their eyes during the test and to respond with "yes" each time the monofilament was sensed. No negative stimuli were tested. At least 8 of 10 correct responses were considered to indicate normal sensibility (18). Less than eight perceived applications indicated reduced sensibility, and when none of the applications were perceived, sensibility to touch was considered absent. Measurements of vibration perception and pressure sensation were performed by trained investigators under supervision of an experienced diabetologist (19) and according to the practical guidelines for the diabetic foot from the American Diabetes Association and the International Diabetic Foot Working Group (5,20). Our choice for these two specific tests lies in their quantitative nature to detect the insensate foot and the fact that both tests are predictors of future foot ulceration (21). Also, the two tests have previously been studied as being the most accurate tools for diagnosing large-fiber polyneuropathy in patients with diabetes. We have validated our clinical DSPN definition against nerve conduction studies as previously described (19).

During the interview on possible neurologic complaints, before undergoing the foot inspection and the neurologic testing, participants were asked whether a physician had ever told them that they were suffering from nerve damage, neuropathy, polyneuropathy, or diabetic foot. We defined subjects with clinical DSPN as being unaware of their disorder if they had answered this question with "no."

Statistical analysis

Follow-up characteristics are presented as means ± SD for normally distributed variables and as median (interquartile range) for variables without a normal distribution. Age- and sex-adjusted differences in characteristics were evaluated for participants with clinical DSPN who were either aware or unaware of their disorder using ANOVA. For log-normal variables, ANOVA was performed on a log scale. *P* values <0.05 were considered to indicate statistical significance. Analyses were performed with the STATA statistical software package (version 11; Stata).

RESULTS—The KORA F4 Survey comprised a total of 1,100 participants with complete information on the presence of clinical DSPN, glucose tolerance status, and other covariables. According

to our definition, clinical DSPN was present in 154 (14%) subjects, only 14 (9%) of whom were classified as being aware of their disorder and as many as 140 (91%) as being unaware. The prevalence of clinical DSPN and subsequent unawareness of having the disorder is presented in Table 1 according to glucose tolerance status. Participants with IFG-IGT and with known diabetes had the highest prevalence of clinical DSPN [23.9% (95% CI 12.6-38.8) and 22.0% (16.2–28.9), respectively]. Among those with IFG-IGT, 10 of 11 (91%) case subjects with clinical DSPN were unaware of having the disorder. This proportion was only slightly lower among those with known diabetes, among whom 30 of 39 (77%) case subjects with clinical DSPN were unaware of having the disorder.

In Table 2, differences in characteristics are presented between participants who were aware of having clinical DSPN and those who were unaware. Compared with the latter, subjects who were aware of their disorder had on average a higher systolic blood pressure and were more likely to have known diabetes. No differences between the two groups were observed for the prevalence of neurologic diseases, the prevalence of prediabetes, foot examinations, and DDMP participation (the latter two variables were only available for participants with known diabetes). With regard to neurologic characteristics, participants aware of having clinical DSPN more often had complaints of pain, paresthesias, and numbness in the feet over the last 24 h; foot ulcers: and absent ankle reflexes. The continuous monofilament test scores showed that

clinical DSPN was more severe in subjects aware of having clinical DSPN as indicated by lower test scores compared with those who were unaware of having the disorder. The continuous tuning fork test scores indicated this as well; yet, only borderline statistical significance was reached.

Information on the performance of a foot examination by a physician was assessed for participants with known diabetes only (n = 177). Excluding those with missing data (n = 10), 113 of 167 (68%) subjects with known diabetes reported to have ever had their feet examined by a physician (Table 3). Of these foot examinations, 88 of 113 (78%) had taken place within the last 12 months and 25 of 113 (22%) had been performed >12 months ago. Approximately one-quarter of the subjects with known diabetes had never undergone a foot examination, and 13 (8%) could not remember. In total, 38 patients with known diabetes had clinical DSNP according to our definition, 29 (76%) of whom were unaware of having the disorder. Eighteen of these 29 (62%) subjects indicated having ever undergone a foot examination by a physician, whereas 8 stated to have never had their feet examined. Thirteen of the 18 (72%) foot examinations had taken place within the last 12 months and 5(18%) > 12 months ago. Of the nine case subjects aware of having clinical DSPN, a foot examination had been performed in seven.

According to the German National Disease Management Guidelines for neuropathy in adults with diabetes, individuals with diabetes should be screened for DSPN at diagnosis and yearly thereafter

Table 1—Prevalence of clinical DSPN according to glucose tolerance status: KORA F4 (2006–2008)

	Clinical DSPN*			
	n	Prevalence of clinical DSPN (95% CI)*	Unawareness of clinical DSPN (%)†	
Total study population ($n = 1,100$)	154	14.0 (12.0–16.2)	91	
Normal glucose tolerance ($n = 577$)	64	11.1 (8.6-13.9)	98	
Isolated IFG $(n = 55)$	3	5.5 (1.1–15.1)	100	
Isolated IGT $(n = 183)$	27	14.8 (10.0-20.7)	89	
IFG-IGT $(n = 46)$	11	23.9 (12.6-38.8)	91	
Newly diagnosed diabetes $(n = 62)$	10	16.1 (8.0-27.7)	100	
Known diabetes ($n = 177$)	39	22.0 (16.2–28.9)	77	

^{*}Defined as the presence of an impaired bilateral foot-vibration perception and/or an impaired bilateral foot-pressure sensation. †Defined by a nonaffirmative answer to the question, "Has a physician ever told you that you have nerve damage, neuropathy, polyneuropathy, or diabetic foot?" in combination with the presence of clinical DSPN.

(7). Of the participants with available information on diabetes duration (n = 154), only 11 of 24 (46%) with a duration ≤ 1 year reported having ever undergone a foot examination by a physician. Of the 49 participants with a diabetes duration of ≤ 5 years, 30 (61%) indicated having ever had their feet examined, and this was also true for 75 of 105 (71%) subjects diagnosed with diabetes > 5 years ago.

CONCLUSIONS—The results of this cross-sectional population-based study demonstrated that a large proportion of subjects with prediabetes and diabetes were unaware of having clinical DSPN. While 113 of 167 (68%) participants with known diabetes had ever undergone a foot examination by a physician, only 7 of the 25 (28%) with clinical DSPN were aware of having clinical DSPN, whereas 18 of these 25 (72%) were unaware of having the disorder. Overall, the majority of the reported foot examinations had been carried out within the preceding 12 months.

The prevalence of unawareness of having clinical DSPN in participants with newly diagnosed diabetes was high. Yet, since these subjects were not receiving regular professional diabetes care, a high proportion of unaware DSPN cases was to be expected. Unexpected, though, was the high prevalence of unawareness of having DSPN among participants with known diabetes. Since these subjects are receiving regular diabetes care, the large proportion of unaware case subjects suggests that the current diabetes care practice may have serious shortcomings concerning appropriate attention to foot care. Next to subjects with diabetes, participants with IFG-IGT showed a strikingly high prevalence of unawareness of having clinical DSPN. In a previous report, we showed that IFG-IGT represents a high-risk group for developing DSPN (19). And since clinical DSPN is a strong risk predictor for the subsequent development of diabetic foot ulcers (21), these prediabetic individuals may also benefit from receiving preventive foot

To date, there are only two publications on the prevalence of undiagnosed DSPN in patients with known type 2 diabetes (13,14). Although a direct comparison of results is hampered by differences in study design, sample size, and assessment of undiagnosed DSPN, the main finding of the two is concordant:

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Table 2—Characteristics of KORA F4 participants according to awareness and unawareness of having clinical DSPN: KORA F4 (2006-2008)

	Clinical DSPN*		
	Aware†	Unaware†	P
General characteristics			
N	14	140	
Male sex	17 (86)	84 (60)	0.058
Age (years)	71.8 ± 4.4	71.9 ± 5.8	0.929
Height (cm)	170 ± 8.4	168 ± 9.0	0.459
BMI (kg/m ²)	29.9 ± 4.5	29.1 ± 4.6	0.512
Waist circumference (cm)	106 ± 12.5	101 ± 12.6	0.394
Systolic blood pressure (mmHg)	138 ± 22.4	127 ± 19.4	0.015
Diastolic blood pressure (mmHg)	74.8 ± 11.6	71.6 ± 11.1	0.193
Hypertension‡	12 (86)	90 (64)	0.106
Current smoking	1 (7)	9 (6)	0.965
High alcohol consumption§	4 (29)	19 (14)	0.811
Low physical activity	8 (57)	85 (61)	0.735
Presence of neurologic disease¶	3 (21)	44 (31)	0.612
Prediabetes	4 (29)	37 (26)	0.103
Newly diagnosed diabetes	0	10 (7)	0.343
Known diabetes	9 (64)	30 (21)	0.001
Foot examination by physician#	7 (78)	18 (62)	0.736
Participation in DDMP**	3 (43)	13 (72)	0.162
Neurologic characteristics			
Pain (feet) in previous 24 h	6 (43)	23 (16)	0.005
Paresthesias (feet) in previous 24 h	8 (57)	29 (21)	0.002
Numbness (feet) in previous 24 h	11 (79)	40 (29)	< 0.001
Dry skin of both feet	10 (71)	73 (52)	0.269
Callus formation on both feet	4 (29)	69 (49)	0.255
Fissures on both feet	3 (21)	12 (9)	0.297
Hallux valgus on both feet	3 (21)	24 (17)	0.595
Charcot foot	0	0	_
Absent ankle reflexes	10 (71)	30 (21)	0.001
Foot ulcer present	2 (14)	1(1)	0.026
Severity of clinical DSPN††			
Monofilament test score	4.8 (1.5-8.5)	7.0 (5.0–10.0)	0.004
Tuning fork test score	0 (0-3.8)	2.5 (2.3-4.5)	0.069

Data are means \pm SD, median (interquartile range), or n (%) unless otherwise indicated. *Defined as the presence of an impaired bilateral foot-vibration perception and/or an impaired bilateral foot-pressure sensation. †Awareness and unawareness of having clinical DSPN was defined as giving either a confirmative or negative answer to the question, "Has a physician ever told you that you have nerve damage, neuropathy, polyneuropathy or diabetic foot?" in combination with the presence of DSPN. ‡Defined as a blood pressure of ≥140/90 mmHg and/or the use of antihypertensive medication in subjects who reported to have been previously diagnosed with hypertension. §For women, ≥20 g/day and for men ≥40 g/day. ||Performing <1 h of physical activity per week during leisure time in either winter or summer. ¶Neurologic diseases comprised conditions that might cause nerve damage, including cancer, stroke, dementia, and hernias. #Data on having one's feet examined by a physician were assessed in patients with known diabetes only. Because of missing data, percentages were based on 9 participants with known diabetes being aware of having clinical DSPN and 29 participants with known diabetes being unaware of having clinical DSPN. **Participation in a type 2 diabetes disease-management program was assessed in participants with known diabetes only. Because of missing data, percentages were based on 7 participants with known diabetes being aware of having clinical DSPN and 18 participants with known diabetes being unaware of having clinical DSPN. ††Severity of clinical DSPN was represented by the continuous scores of the monofilament test and tuning fork test. The average score of the left- and right-sided test was calculated, with lower test scores indicating a higher severity of clinical DSPN.

DSPN was underdiagnosed in over onehalf of the diabetic patients. Wang et al. (14) have speculated that the underdiagnosis in their population sample might be the result of the low number of foot examinations performed by a health professional, since only 16.2% of their study sample had received preventive foot care. Herman and Kennedy did not have data on foot examinations (13). It is known that a large proportion of diabetic foot complications are preventable and

that regular foot examinations by a general practitioner, a physician, or other health care providers play an important role in prevention (5). As such, a number of studies have reported on (frequency of) preventive foot care in individuals with diabetes (8,11,14,22-25). An Australian population-based cohort study on diabetes care practice reported that only 50% of the 396 participants with known type 2 diabetes had received a foot examination by a health professional within the last 12 months (11). Of those who were classified as being at risk for a future foot ulcer, only 46 of 81 (57%) reported to have had a foot examination. Another large cohort study of 3,564 patients with type 2 diabetes randomly selected from outpatient clinics and general practitioners found similar results (8). As many as 50% of these patients reported not to have had their feet examined in the last 12 months. And among the patients with symptomatic neuropathy or peripheral vascular disease—both risk factors of foot complications—over onethird had not undergone a foot examination. In summary, the general picture sketched by the previous literature on diabetes care is that attention to foot complications was poor and that a large proportion of patients were not offered regular foot examinations—not even those at high risk for developing foot complications. Whereas our data on preventive foot care are less elaborate, our findings fit this picture of insufficient and inadequate practice of preventive foot care. In addition, case subjects aware of having clinical DSPN showed a significantly higher proportion of absent ankle reflexes and foot ulcers compared with case subjects who were unaware of having DSPN (Table 2). Whereas there were no differences between the two groups concerning abnormal test scores on monofilament and tuning fork tests (data not shown), we can only speculate that overall, ankle reflex testing and the presence of ulcers have been the only criteria used to diagnose DSPN and that foot examinations were thus not performed according to clinical guidelines (7).

Some limitations and strengths of our study need to be discussed. First, the data on previous foot examinations being performed are self-reported and may suffer from recall bias. Also, the question of whether a physician has ever told the participant that he/she was suffering from nerve damage, neuropathy, polyneuropathy, or diabetic foot may also be subject to recall bias. Yet, the latter data were

Table 3—Performance of a foot examination by a physician on participants with known diabetes: KORA F4 (2006–2008)

Foot examination by a physician*		Subjects without clinical DSPN†	Subjects with clinical DSPN†	
	All subjects with known diabetes		Aware of having clinical DSPN‡	Unaware of having clinical DSPN§
N	167	129	9	29
Yes	113 (68)	88 (68)	7 (78)	18 (62)
Within last 12 months	88 (78)	71 (81)	4 (57)	13 (72)
>12 months ago	25 (22)	17 (19)	3 (43)	5 (28)
No	41 (24)	32 (25)	1 (11)	8 (28)
Unknown	13 (8)	9 (7)	1 (11)	3 (10)

Data are n (%) unless otherwise indicated. *Participants were asked, "When has a physician examined your feet lately?" Answer options A (within the past 12 months) and B (>12 months ago) were combined to indicate that a foot examination had ever taken place. Answering option C (not ever) indicated that a foot examination had never taken place, and option D (I don't know) indicated an unknown status regarding the performance of a foot examination. †DSPN was defined as the presence of an impaired bilateral foot-vibration perception and/or an impaired bilateral foot-pressure sensation. ‡As defined by a confirmative answer to the question, "Has a physician ever told you that you have nerve damage, neuropathy, or diabetic foot?" in combination with the presence of DSPN. §As defined by a nonaffirmative answer to the question, "Has a physician ever told you that you have nerve damage, neuropathy, polyneuropathy, or diabetic foot?" in combination with the presence of DSPN.

collected by a trained interviewer (aware of the importance of this specific information) before the actual neurologic examination of the participant took place. It is unlikely that false memory may have had a substantial effect on our results and conclusion. Second, there is no uniform consensus on a definition of diagnosing DSPN for use in epidemiological studies. Also, we cannot rule out that our definition of clinical DSPN allowed for the inclusion of some case subjects that had developed DSPN due to a different cause rather than to chronic hyperglycemia. Subsequently, we performed a validation study to strengthen the validity of the present findings, and we observed that our clinical DSPN definition had an excellent diagnostic performance (19). A further strength of the current study includes the use of different bedside tests of peripheral sensory function, facilitating the construction of a relatively accurate definition of clinical DSPN.

In conclusion, our findings show a high prevalence of unawareness of having clinical DSPN among subjects with prediabetes and with diabetes. The high frequency of unawareness among the latter group is of particular concern, given that subjects with diabetes receive regular diabetes care. Despite the performance of foot examinations by a physician, the proportion of subjects with known diabetes unaware of having DSPN is high. Overall, these results suggest inadequate attention to diabetic foot prevention practice and insufficient adherence to the clinical guidelines for diabetes care necessary

to prevent further development of severe diabetic foot complications.

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