



Screening and diagnosis of diabetic polyneuropathy in clinical practice: A survey among German physicians (PROTECT Study Survey)

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ABSTRACT

Aims: We sought to obtain detailed information on the procedures and appraisal of screening for and diagnosing diabetic sensorimotor polyneuropathy (DSPN) in clinical practice.

Methods: This cross-sectional survey included 574 physicians from 13 federal states across Germany who responded to a tripartite questionnaire.

Results: The vast majority of the respondents reported to screen for DSPN at least once a year (87 %), while 65 % reported to examine the feet of DSPN patients at least twice a year. However, only 28 % and 20 % of the respondents used questionnaires and scores to assess the severity of neuropathic symptoms and signs, respectively. The rates of participants reporting that they do not use a standardized testing procedure were 58 % for pressure sensation, 62 % for pain sensation, and 54 % for thermal sensation. The rates of respondents reporting that they do not deploy a standardized assessment were 41 % for vibration sensation, 73 % for pressure sensation, 77 % for pain sensation, and 66 % for thermal sensation. Half of the physicians oriented themselves towards clinical guidelines when diagnosing DSPN.

Conclusions: Despite relatively high screening rates, the willingness to implement both standardized testing procedures and assessment and to follow guidelines is low among physicians when screening for and clinically diagnosing DSPN.

1. Introduction

Diabetic sensorimotor polyneuropathy (DSPN) has been clinically defined as the presence of symptoms and/or signs of peripheral nerve dysfunction in patients with diabetes after the exclusion of other causes [1]. Although DSPN affects around one third of people with diabetes and exerts a major clinical impact on prognosis, quality of life, and morbidity primarily due to neuropathic pain and foot ulcers, the condition remains often underdiagnosed and undertreated in clinical practice [1–3]. The challenges of diagnosing DSPN include the insidious disease onset in the absence of reliable biomarkers to predict which patients will develop neuropathic pain and which will remain asymptomatic or painless [4]. Moreover, there is a lack of a uniform DSPN definition, generally

accepted diagnostic criteria, and standardized testing procedures for the multitude of diagnostic tools used [5], and disparities exist between physician and patient perceptions around the diagnosis and treatment of painful DSPN [6].

A major obstacle in establishing adequate management of DSPN is the lack of awareness of this complication of diabetes by physicians and patients alike. Several studies suggest that people with diabetes are frequently unaware of having neuropathy [7–10] or diabetic foot disease [11,12]. In a survey from Spain, diabetic foot screening was performed only in 37 % of patients with diabetes in primary care [13]. Moreover, both physicians and patients are still underestimating the clinical impact of DSPN. In a large US nation-wide survey, physicians reported a neuropathy prevalence of 18 %, but subsequent

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monofilament testing detected a prevalence of 37 % in type 2 diabetes patients [14]. In the cross-sectional PROTECT Study, we reported that painful and painless DSPN remained undiagnosed in 57 % and 82 % of type 2 diabetes patients, respectively [2]. The PROTECT Study follow-up survey showed that the intensity of neuropathic symptoms in the feet increased over 2.5 years in approximately one half of the respondents, but more than one third did not receive any pharmacotherapy for these symptoms [15]. Likewise, in a web survey from Japan, participants with diabetes who experienced bilateral foot pain or numbness reported a low level of satisfaction with treatment for pain [16].

Several guidelines provide information on how to diagnose and screen for DSPN in clinical practice [1,3,17], but studies that assessed how these recommendations are being implemented in the real-world setting are scarce. One factor that may contribute to underdiagnosis and undertreatment of DSPN in daily practice could be a poor acceptance of and adherence to clinical guidelines [18]. A survey among

German family practitioners indicated that only 51 % were clearly positive about guidelines, considering them to be associated with benefits for patient care [19].

Against this background we conducted a survey among German general practitioners (GPs), internists, and diabetologists to obtain detailed information about how they assess DSPN, particularly focusing on which instruments, scoring systems and specific testing procedures at which degree of standardization they use and whether they orient themselves towards guidelines when screening for and diagnosing DSPN in their daily routine.

2. Methods

The present study was a cross-sectional survey among GPs, internists, and diabetologists conducted by the nationwide educational initiative (“Diabetes! Do you listen to your feet?”) in Germany. The aim was to

Table 1

General questions.

What applies to your medical qualification? ^a (n = 574)	n (%)
General practitioner	437 (76)
Internist	161 (28)
Diabetologist	61 (11)
Does your practice participate in a Disease Management Program (DMP) for diabetes or is it a specialized medical practice for diabetes? ^a (n = 573)	
Participation in DMP for type 1 diabetes	177 (31)
Participation in DMP for type 2 diabetes	491 (86)
Specialized for diabetes	61 (11)
Nothing applicable	67 (12)
How many patients do you have in your practice per quarter? (n = 559)	
< 1000	143 (26)
1000–1500	243 (43)
> 1500	173 (31)
How many of your patients have diabetes? (n = 567)	
~10 %	250 (44)
< 10 %	76 (13)
> 10 %	241 (43)
How often per year do you screen your diabetes patients routinely for polyneuropathy? (n = 564)	
< 1 time per year	73 (13)
1 time per year	298 (53)
> 1 time per year	193 (34)
How often do you examine the feet of your diabetes patients with known polyneuropathy? (n = 268)	
< 2 times per year	199 (35)
2–4 times per year	283 (50)
> 4 times per year	86 (15)
Do you apply clinical scores/questionnaires to assess symptoms of diabetic polyneuropathy? (n = 567)	
No	409 (72)
Yes, namely: ^a	158 (28)
Visual Analog Scale (VAS) pain	71 (45)
Numerical Rating Scale (NRS) pain	55 (35)
Neuropathy Symptom Score (NSS)	81 (51)
Total Symptom Score (TSS) / NTSS-6	14 (9)
Michigan Neuropathy Screening Instrument (MNSI) part A	7 (4)
Others	8 (5)
Do you apply clinical scores to assess neuropathic deficits/signs? (n = 559)	
No	449 (80)
Yes, namely: ^a	110 (20)
Neuropathy Disability Score (NDS)	84 (76)
Michigan Neuropathy Screening Instrument (MNSI) part B	16 (15)
Neuropathy Impairment Score – Lower Limbs (NIS-LL)	4 (4)
Others	8 (7)
Do you orient yourself towards a guideline during your assessment of diabetic polyneuropathy (n = 562)	
No	266 (47)
Yes	296 (53)

^a multiple answers possible

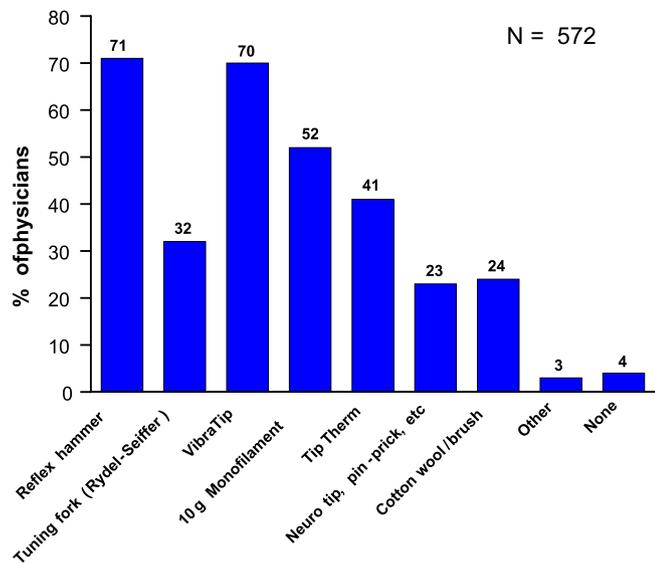


Fig. 1. Which instruments do you routinely use for the examination of diabetic polyneuropathy? (multiple answers possible).

obtain detailed information on the process and procedures of screening and diagnosis of DSPN in daily clinical practice. The questionnaire for the survey, including multiple-choice (single- and multi-select) as well as open-ended questions written and conducted in German, was developed by an expert panel comprising five diabetologists and one neurologist based on the current literature and their clinical experience. The first part of the anonymous questionnaire was designed to capture information about the participating physicians' medical qualification and specialization of their practices. The second part aimed at collecting general information about screening frequency, use of clinical neuropathy scores, adherence to guidelines, and utilization of bed-side tests. The objective of the third part of the questionnaire was to assess if physicians adhere to a standardized procedure for the different bedside tests (vibration, pressure, pain and temperature sensation) in terms of testing site, test procedure, and test assessment.

The questionnaire was distributed in paper-based format among GPs, internists, and diabetologists across all federal states of Germany from

February 2020 until December 2020. Physicians were recruited off-line and randomly selected from a private contact database. As expense allowance for the time invested (approximately 10 min), participating physicians received a Twintip instrument for use in their daily practice. In total, 1440 questionnaires were distributed, and 580 physicians from 13 out of 16 federal states of Germany participated in the survey (response rate: 40.3 %), 18.8 % from North Rhine-Westphalia, 12.8 % from Baden-Württemberg, 11.9 % from Hessen, 11.7 % from Bavaria, 11.5 % from Berlin, 8.2 % from Lower Saxony, 7.8 % from Saxony, 6.0 % from Brandenburg, 4.6 % from Rhineland-Palatinate, 2.9 % from Schleswig-Holstein, 2.0 % from Saarland, 1.6 % from Thuringia and 0.2 % from Saxony-Anhalt. Statistical analysis comprised descriptive statistics including categorical data with absolute or relative frequencies.

3. Results

Table 1 shows the general questions addressing the medical qualification, patient flow and characteristics, the use of clinical scores to assess neuropathic symptoms and signs, and orientation towards guidelines. The vast majority of the participating physicians were GPs (76 %), followed by internists (28 %) and diabetologists (11 %) (multiple entries possible), and 86 % participated in a disease management program for type 2 diabetes. The vast majority of the respondents reported to screen for DSPN at least once a year (87 %), while 65 % reported to examine the feet of patients with DSPN at least twice a year. Respondents who reported to use clinical scores or questionnaires to assess symptoms associated with DSPN most frequently employed the Neuropathy Symptom Score (NSS) (51 %) and visual analog scale (VAS) for pain (45 %), whereas 72 % reported not to use such instruments. Those respondents who reported the use of clinical scores to assess the severity of neuropathic signs most frequently employed the NDS (76 %), whereas 80 % reported not to apply such scores.

The answers to the question which instruments are routinely used in the examination of DSPN are shown in Fig. 1. The most frequently used tools were the reflex hammer (71 %) and the VibraTip (70 %), followed by the 10 g monofilament (52 %), TipTherm (41 %) and Rydel-Seiffer tuning fork (32 %).

The results for the questions about testing the distribution pattern of neuropathic signs and the use of the Rydel-Seiffer tuning fork to assess vibration sensation are given in Table 2. The tuning fork was most frequently applied at several sites (80 %), while the remaining

Table 2

Questions about testing the distribution pattern of neuropathic signs and how the Rydel-Seiffer tuning fork to assess vibration sensation is being used.

Which tests do you apply at several sites to assess the distribution pattern (e.g. stocking like pattern) of neuropathic deficits/signs? ^a (n = 400)	n (%)
Test of vibration sensation (tuning fork)	320 (80)
Test of pressure sensation (10 g-Monofilament)	228 (57)
Test of pain sensation	186 (47)
Test of temperature sensation	213 (53)
I perform all tests only at one site each	40 (10)
Test of vibration sensation with Rydel-Seiffer tuning fork (Where do you preferentially test vibration sensation?) ^a (n = 398)	
Dorsal big toe dorsal (interphalangeal joint)	132 (33)
Medial metatarsophalangeal joint	190 (48)
Dorsum of the foot	122 (31)
Ball of the foot	61 (15)
Medial malleolus	237 (60)
Patella	47 (12)
Other site	13 (3)
I do not have a standard examination site	19 (5)
Starting from which value (scale 0.0 – 8.0) do you rate the vibration sensation at the above indicated examination site as “reduced”? (n = 354)	
Depending on the age of the patient	63 (18)
Independent of the age of the patient	141 (40)
Other assessment method	3 (1)
I do not use a standardized assessment	147 (41)

^a multiple answers possible

Table 3

Questions related to the use of the 10 g monofilament to assess pressure sensation.

Test of pressure sensation with 10 g monofilament (Where do you preferentially test pressure sensation?) ^a (n = 371)	n (%)
Dorsal big toe	100 (27)
Plantar big toe	128 (35)
Plantar toes D2-D5	77 (21)
Ball of the foot (metatarsal)	157 (42)
Plantar big toe and ball of the foot (metatarsal)	96 (26)
Other site	12 (3)
I do not use a standardized examination site	43 (11)
How often do you apply the monofilament to the above mentioned area of each foot? (n = 312)	
1–3 times	53 (17)
4–6 times	62 (20)
≥ 7 times	16 (5)
I do not use a standardized procedure	181 (58)
Starting from how many false answers do you rate the pressure sensation as „reduced“? (n = 274)	
1–2	51 (19)
3–4	16 (6)
≥ 5	5 (2)
I do not use a standard assessment	201 (73)

^a multiple answers possible**Table 4**

Questions related to the assessment of pain sensation.

Test of pain sensation using a pointed object (e.g. Neurotip, pin-prick, tooth pick) (Where do you preferentially test pain sensation?) ^a (n = 352)	n (%)
Dorsal big toe	79 (22)
Plantar big toe	92 (26)
Dorsal foot	143 (41)
Plantar foot	190 (54)
Other site	12 (3)
I do not use a standardized examination site	55 (16)
How often do you apply the instrument to the above mentioned area of each foot? (n = 299)	
1–3 times	62 (21)
4–6 times	46 (15)
≥ 7 times	7 (2)
I do not use a standardized procedure	184 (62)
Starting from how many false answers do you rate the pain sensation as „reduced“? (n = 280)	
1–2	59 (17)
3–4	13 (5)
≥ 5	3 (1)
I do not use a standardized assessment	215 (77)

^a multiple answers possible**Table 5**

Questions related to the assessment of thermal sensation.

Test of temperature sensation using the TipTherm, cold tuning fork or ice cold test tube (Where do you preferentially test temperature sensation?) ^a (n = 361)	n (%)
Big toe dorsal	78 (22)
Big toe plantar	66 (18)
Dorsum of the foot	212 (59)
Ball of the foot	129 (36)
Other site	20 (6)
I do not use a standardized examination site	57 (16)
How often do you apply the instrument to the above mentioned area of each foot? (n = 323)	
1–2 times	62 (19)
3–5 times	72 (22)
≥ 6 times	14 (5)
I do not use a standardized procedure	175 (54)
Starting from how many false answers do you rate the temperature sensation as “reduced“? (n = 317)	
1–2	86 (17)
3–4	20 (6)
≥ 5	3 (1)
I do not use a standardized assessment	208 (66)

^a multiple answers possible

instruments were used at several sites by around half of the respondents. The Rydel-Seiffer tuning fork was most frequently applied at the medial malleolus (60 %), followed by the medial metatarsophalangeal joint (48 %). Only 18 % of the respondents rated vibration sensation assessed by the Rydel-Seiffer tuning fork as being abnormal depending on the age of the patient, while 40 % reported age-independent rating and 41 % reported that they do not use a standardized approach when assessing vibration sensation.

The results for the questions related to the use of the 10 g monofilament to assess pressure sensation are given in Table 3. The 10 g monofilament was most frequently applied at the metatarsal ball of the foot (42 %), followed by the plantar aspect of the big toe (35 %). While 58 % of the respondents reported that they do not apply a standardized testing procedure, 73 % reported that they do not use a standardized assessment of pressure sensation.

The results for the questions related to the assessment of pain sensation are listed in Table 4. Pain sensation was preferentially tested on the plantar (54 %) and dorsal (41 %) aspects of the foot, respectively. While 62 % of the respondents reported that they do not apply a standardized testing procedure, 77 % reported that they do not use a standardized approach when assessing pain sensation.

The results for the questions related to the assessment of thermal sensation are shown in Table 5. Thermal sensation was preferentially tested on the dorsum of the foot (59 %), followed by the ball of the foot (36 %). While 54 % of the respondents reported that they do not use a standardized testing procedure, 66 % reported that they do not apply a standardized assessment of thermal sensation.

4. Discussion

The results of this survey indicate that despite regular screening for DSPN by the vast majority of GPs, internists, and diabetologists, most of them neither used clinical questionnaires and scores to assess the severity of neuropathic symptoms and signs nor applied a standardized procedure or appraisal when testing for vibration, pressure, pain, or thermal sensation. Furthermore, to diagnose or exclude DSPN, only half of the physicians oriented themselves towards guidelines. These data suggest that physicians are commonly not ready to use both standardized testing procedures and assessment and to follow clinical guidelines in their daily practice of managing patients with DSPN.

Only a few previous studies reported on the modalities of DSPN assessment by healthcare providers in clinical practice. A cross-sectional survey administered to GPs and diabetes specialists in France, Italy, Spain, and the United Kingdom showed that the diagnostic procedures for and prevalence rates of DSPN varied considerably across these countries and that DSPN diagnosis was primarily based on symptoms. However, 24 % and 27 % of patients diagnosed with DSPN had no records of neuropathic symptoms and neurological examination, respectively, and the proportion of patients with DSPN who did not receive treatment specific to the condition ranged from 32 % to 42 % [20]. In a survey from five countries in South-East Asia, 35–88 % of the patients with painful DSPN were reported by primary care physicians and practitioners as not being screened for the condition in a typical month [6]. An online survey of healthcare providers from the US found that while 83 % of diabetes patients reported symptoms of painful DSPN, only 41 % of these patients had been diagnosed with DSPN. Almost two thirds of the healthcare providers never had their patients complete a DSPN assessment questionnaire, and only 41 % performed specific diagnostic tests on all patients who had reported DSPN symptoms [21].

The percentages of physicians using screening tests for DSPN in patients with diabetic foot problems were reported in two studies. A Diabetic Foot Education Program from India conducted a survey of physicians from diabetic foot clinics, among whom 67 % reported to use a monofilament to assess pressure sensation, while 76 % and 60 % stated to assess vibration sensation using a tuning fork and a biothesiometer, respectively [22]. In an online survey among GPs in France, UK, Spain,

and Germany on the perception and knowledge of the management of diabetic foot ulcers, a high degree of heterogeneity across these countries was reported regarding the percentages of GPs employing tests to screen for DSPN [23]. Overall, neurological testing was carried out by 30 %, 39 %, 41 %, and 80 % of the GPs in France, UK, Spain, and Germany, respectively. The corresponding numbers were 16 %, 9 %, 20 %, and 15 % for monofilament testing, while the percentages were 1 %, 3 %, 5 %, and 43 % for testing of vibration sensation. The percentages of GPs carrying out other tests such as examination of tendon reflexes, pin-prick test, and thermal sensation testing were extremely low in France, UK, and Spain (0–2 %), albeit higher with 7 %, 4 %, and 19 % in Germany [23]. Altogether, these data point to insufficient screening rates for DSPN with considerable regional differences in diabetic foot patients.

However, in contrast to the present study, none of the aforementioned reports conducted a detailed survey on the individual procedures of using bedside instruments, clinical neuropathy scores, and adherence to standardization and guidelines. We extend the current knowledge by revealing that while most physicians adhere to the current clinical guidelines with respect to the frequency of screening for DSPN [1,17], they are reluctant to using questionnaires and scores to assess the severity of neuropathic symptoms and signs or a standardized testing procedure and appraisal as recommended by some guidelines [17]. However, given the subjective nature of the available tests and the lack of uniform diagnostic criteria for DSPN, a certain degree of standardization using appropriate cut-offs is desired to avoid diagnostic bias. For example, since tuning fork test results markedly decline physiologically with increasing age [24], age-dependent normal ranges should be applied when classifying vibration sensation as being abnormal or normal. Indeed, when using a tuning fork, neurologists and diabetologists neuromuscular physicians tend to overestimate vibration sensation loss, and it has even been suggested that to improve assessment of vibration sensation, physicians should take into account height and weight (or body surface area) apart from age when judging vibration abnormalities [25].

Clinical guidelines are intended to offer concise instructions on how to provide healthcare services [26], and several of these are available on the screening and diagnosis of DSPN [1,3,17], but the physicians' adherence to these guidelines is not known. A recent survey among US neurologists reported a considerable variation in the strategies employed to diagnose and treat chronic inflammatory demyelinating polyradiculoneuropathy (CIDP), despite the existence of an international guideline [18]. In the present survey, only half of the physicians oriented themselves towards guidelines when diagnosing DSPN. Likewise, a recent survey among German GPs reported that only 51 % were clearly positive about guidelines, while 43 % perceived their implementation as being complicated and 59 % felt that guidelines are restricting the freedom of action for physicians [19]. To overcome these hurdles, it has been suggested to specifically address the expectations of GPs on the deliverables provided by guidelines to foster their attractiveness for general medical care, e.g. by securing a simple applicability and clarity, reducing the complexity, providing adequate medical scope, leaving options for delegation to other staff members, and involving GPs in the guideline development process [19].

The strength of this work is the detailed survey on the procedures of using screening instruments, clinical neuropathy scores as well as readiness to standardization and adherence to guidelines of physicians managing patients with DSPN. The limitations include the potential for selection bias of the participating physicians, the unequal distribution of the specialties included, and limited generalizability of the results. The response rate of 40.3 % in the survey may have introduced another source bias, as only the most motivated physicians and those with special interest in DSPN may have filled the questionnaire. However, the physicians' response rate reported herein was well within the wide range from 4 % to 80 % observed in other surveys focusing on DSPN [6, 27].

In conclusion, this survey revealed that the vast majority of GPs, internists, and diabetologists perform regular screenings for DSPN as suggested by clinical guidelines. However, the testing procedures applied to this end are heterogeneous, not standardized, and do not consider disease severity, and, hence, are subject to diagnostic bias. Thus, physicians are commonly not ready to use both standardized testing procedures and assessment and to follow clinical guidelines in their daily practice of managing patients with DSPN. The possible reasons for obvious gaps between academic requirement and real-world practice should be explored.

CRedit authorship contribution statement

DZ wrote the manuscript. DZ, AS, RLa, RL, KhR, KR, and OS researched data, contributed to discussion and reviewed and edited the manuscript. DZ is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Conflict of Interest

DZ, RL, KhR, KR, and OS are advisory board members of the National Education Initiative and received honoraria for speaking activities from Wörwag Pharma. DZ and AS received research grants from Wörwag Pharma. RLa received a grant for prevention activities for the German Diabetes Foundation.

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