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Painful and painless neuropathies are distinct and largely undiagnosed entities in subjects participating in an educational initiative (PROTECT study)



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ABSTRACT

Aims: We conducted a nationwide educational initiative to determine the prevalence and risk factors of diagnosed and undiagnosed painful and painless distal sensory polyneuropathy (DSPN).

Methods: Among 1850 participants, 781 had no history of diabetes (ND), 126 had type 1 diabetes (T1D), and 943 had type 2 diabetes (T2D). Painful DSPN was defined as polyneuropathy detected by bedside tests with pain and/or burning in the feet, while painless DSPN was defined as polyneuropathy with paresthesias, numbness, or absence of symptoms.

Results: DSPN was detected in 48.2% of ND, 44.3% of T1D, and 55.3% of T2D subjects. DSPN was painful, painless, or atypical in 62.1, 24.8, and 13.1% of the participants. Painful DSPN was more severe than painless DSPN. Painful and painless DSPN were previously undiagnosed in 61.5 and 81.1% of the participants, respectively. In T2D subjects, painful and painless DSPN were associated with a higher and lower BMI, respectively. Among ND participants 39.2% had HbA1c levels indicating prediabetes/diabetes.

Conclusions: Around half of participants in an educational initiative had DSPN, 62% of whom had the painful entity that correlated with BMI in T2D. Since many cases of neuropathy and diabetes remain undiagnosed, effective strategies to timely detect both conditions should be implemented.

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1. Introduction

Most common among diabetic neuropathies is chronic distal sensory polyneuropathy (DSPN), accounting for about 75% of diabetic neuropathies [1] and affecting about one third of all diabetic patients [2]. DSPN manifests mainly as a painful entity with neuropathic pain as a hallmark and a painless variant which may culminate in foot ulceration [3]. A simple definition of DSPN for clinical practice is the presence of symptoms and/or signs of peripheral nerve dysfunction in people with diabetes after the exclusion of other causes [1]. Pain associated with DSPN exerts a substantial impact on the quality of life, particularly by causing considerable interference in sleep and enjoyment of life [2]. Chronic painful DSPN is encountered in 13–26% of diabetic patients [2]. In a general-population health survey conducted in the US, the prevalence estimate of probable neuropathic pain using the PainDetect questionnaire amounted to 10% [4]. Pain is a subjective symptom of major clinical importance as it is often this complaint that motivates patients to seek health care. Regrettably, in one UK survey only 65% of diabetic patients received treatment for their neuropathic pain [5]. On the other hand, up to 50% of diabetic peripheral neuropathies may be asymptomatic. If not recognized and if preventive foot care is not implemented, patients are at risk for injuries to their insensate feet [1]. The prevalence of DSPN, defined as ≥ 1 insensate area based on monofilament testing, in the US adult population >40 years of age was 15% [6].

Bed-side screening instruments to detect clinically manifest DSPN such as the tuning fork and 10 g monofilament have been shown to predict diabetic foot ulcers [7,8]. Consequently, the American Diabetes Association (ADA) recommends that all patients should be assessed for DSPN starting at diagnosis of type 2 diabetes and 5 years after the diagnosis of type 1 diabetes and at least annually thereafter [1]. However, neuropathy screening is underutilized in primary care practice [9,10]. In a recent survey from Spain, diabetic foot screening was performed only in 37% of patients with diabetes in primary care [11]. Moreover, the clinical impact of DSPN is still being underestimated by both physicians and patients. In a large US nation-wide survey, physicians reported a neuropathy prevalence of 18%, but subsequent monofilament testing detected a prevalence of 37% in type 2 diabetes patients. Moreover, physicians prospectively identified only 31% and 66% of patients with mild/moderate and severe neuropathy, respectively [12].

Moreover, people with diabetes are frequently unaware of having neuropathy [13–15]. We previously reported that more than half of the first 983 subjects from this nationwide educational initiative with and without diabetes had DSPN which was reported as previously undiagnosed by two thirds [16]. However, data on neuropathic symptoms including pain were not reported and in a substantial proportion of these patients demographic and clinically relevant data such as BMI and HbA1c were not available [16]. The present final analysis comprising 1850 participants with a considerably more robust database aimed to estimate the rates of (1) painful and pain-

less DSPN and to identify the associated risk factors, (2) previously undiagnosed painful and painless DSPN in participants with and without history of diabetes, and (3) prediabetes and diabetes in persons without history of diabetes.

2. Subjects, materials and methods

2.1. Study population

This nationwide educational initiative (Nationale Aufklärungsinitiative [NAI]) “Diabetes! Do you listen to your feet?” (PROTECT study) was conducted in accordance with the Declaration of Helsinki and was approved by the ethics committee of Heinrich Heine University, Düsseldorf, Germany. All participants provided a written informed consent. From May 2013 through November 2016, 70 action days with promotional stands have been performed nationwide in 47 cities in Germany, 13 of which were organized in shopping centers and 34 in diabetes and health care fairs including >25,000 visitors, 1850 of whom underwent a foot examination. Visitors attending the promotional stand were also invited to test their foot sensation by walking over a barefoot course with four different floorings. Furthermore, educational measures included lectures and consultations with experts about diabetes and diabetic neuropathy given by diabetologists at the promotional stand, consultations by the podologists during and after the foot examination, broad public relations activities by print, online, and broadcasting media, news services, editorial media reports, and distribution of information material at the promotional stand (newsletter, brochures, guides, etc.), regional letters of announcement to physicians and pharmacists, and nationwide information letters to (around 50,000) general practitioners and diabetologists. Each year since 2013, a press conference for the specialist and end-user media was held on the occasion of the annual congress of the German Diabetes Association. The NAI website (www.hoerensieaufhreffuesse.de) is the central online platform for all activities and information provided by NAI. As an added value, it features a video consultation by five diabetologists/neurologists on topics related to diabetes and neuropathy.

2.2. Methods

Study participants with or without known diabetes underwent a foot examination and completed a questionnaire including age, sex, history of type 1 or type 2 diabetes and answered the following questions: (1) “Have you ever been diagnosed with neuropathy?”, (2) “Are you currently being treated by a physician because of neuropathy?”

Foot examination was carried out by certified podologists in quiet ambience in a mobile cube (9 m²) with a sliding door closed and included bilateral assessment of pressure, temperature, and vibration sensation which were tested two times on each site and foot. The subject was asked to close his eyes during each test. Pressure perception was determined twice on the plantar aspect of each second metatarsal head using

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