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Original Research

## Prevalence of Painful Diabetic Neuropathy Using the Self-Completed Leeds Assessment of Neuropathic Symptoms and Signs Questionnaire in a Population with Diabetes



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## ABSTRACT

**Objective:** This study assessed the feasibility of diagnosing painful diabetic neuropathy (PDN) using a postal self-completed Leeds Assessment of Neuropathic Symptoms and Signs (S-LANSS) questionnaire, and it compared the prevalence of PDN in patients with diabetes attending primary and secondary care. **Methods:** This was an observational study in northwest England, United Kingdom (n=204). S-LANSS were used by post to diagnose PDN. Consent for participation and access of blood results were obtained from the subjects with diabetes. Ethical approval was granted to do the work.

**Results:** In this study the prevalence of PDN was 30.3%, comprising 33.1% of patients with type 2 diabetes compared to 14.1% patients with type 1 diabetes. The overall prevalence of PDN was 33% (n=43) in the secondary care group and 25.6% (n=19) in the primary care group; the rates were not statistically significant. There were no gender differences between the primary and secondary care populations. There was a significant association of obesity, smoking and height in males with PDN compared to the non-PDN group (p<0.05). There was a significant trend toward increasing prevalence of PDN with duration of diabetes, increasing glycated hemoglobin and increasing body mass index (p<0.05).

**Conclusion:** The overall prevalence of PDN in this study was 30.3%. The results demonstrated the use of self-administered S-LANSS was easy and can be used for epidemiologic surveys of PDN. The results are comparable to and similar to other published series, in both primary and secondary care settings.

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## R É S U M É

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neuropathie diabétique douloureuse

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**Objectif :** L'étude rapportée ici évaluait la faisabilité du diagnostic de la neuropathie diabétique douloureuse (NDD) à l'aide du questionnaire autoadministré S-LANSS (self-completed Leeds Assessment of Neuropathic Symptoms and Signs), qui a été acheminé par la poste, et comparait la prévalence de la NDD chez les patients atteints de diabète qui reçoivent des soins primaires et secondaires.

**Méthodes :** Il s'agissait d'une étude observationnelle réalisée en Angleterre du Nord-Ouest, au Royaume-Uni (n=204). Le questionnaire S-LANSS pour diagnostiquer la NDD a été acheminé par la poste. Les sujets souffrant de diabète ont donné leur consentement à la participation et à l'accès aux résultats des analyses sanguines. L'approbation éthique pour faire les travaux a été accordée.

**Résultats :** Dans l'étude décrite ici, la prévalence de la NDD était de 30,3 % et comportait 33,1 % de patients souffrant du diabète de type 2 par rapport à 14,1 % de patients souffrant du diabète de type 1. La prévalence globale de NDD était de 33 % (n=43) dans le groupe recevant des soins secondaires et de 25,6 % (n=19) dans le groupe recevant des soins primaires. Les taux n'étaient pas statistiquement significatifs. Il n'y avait aucune différence sexuelle entre les populations recevant des soins primaires et les populations recevant les soins secondaires. Il y avait une association significative de l'obésité, du tabagisme et de la taille des hommes atteints de NDD par rapport au groupe sans NDD (p<0,05). Il existait une tendance significative à l'augmentation de la prévalence de NDD et la durée du diabète, l'augmentation de l'hémoglobine glyquée et l'augmentation de l'indice de masse corporelle (p<0,05).

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**Conclusion :** Dans l'étude rapportée ici, la prévalence globale de la NDD était de 30,3 %. Les résultats démontraient que l'utilisation du questionnaire autoadministré S-LANSS était facile et qu'il pouvait être utilisé pour les enquêtes épidémiologiques sur la NDD. Les résultats sont comparables et semblables à d'autres séries publiées dans des contextes de soins primaires et secondaires.

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## Introduction

Diabetes mellitus affects about 382 million people worldwide, and its prevalence is expected to increase to 592 million by the year 2035 (1). Diabetic neuropathy (DN), a well-known, long-term complication of diabetes, can affect almost half of the population with diabetes (2) and is associated with higher rates of morbidity and mortality (3). DN encompasses a variety of clinical and sub-clinical presentations. Painful diabetic neuropathy (PDN) is a common type of diabetic neuropathy and is the most common cause of neuropathic pain (4). The reported prevalence of PDN varied from 11% in Rochester, Minnesota, United States, (5) to 53.7% in the Middle East (6). One study published in the United Kingdom in 2011 reported that the prevalence of PDN was 21.5% in patients with type 2 diabetes and 13.4% in patients with type 1 diabetes, resulting in an overall prevalence of 21% (7). Several studies have observed that the duration of diabetes and increasing age are directly related to PDN (6–11). In the large prospective self-completed Leeds Assessment of Neuropathic Symptoms and Signs (S-LANSS) study in 16 European countries, almost one-quarter of patients with type 1 diabetes developed new-onset painful DN over a 7-year period (8). A prospective study in Finland followed newly diagnosed diabetes patients between the ages of 45 and 64 years for 10 years. It found a 6% prevalence at the time of diagnosis of diabetes and a 26.4% prevalence at the 10-year follow up (9). Most studies found no significant differences according to gender; however, Abbot et al (7) reported a slightly higher prevalence of painful symptoms of neuropathy in females (38%) than in males (31%). The same study also found a higher prevalence of painful symptoms in South Asians (38%) than in Europeans (32%).

Several validated diagnostic questionnaires are available to aid in the diagnosis of neuropathic pain, including the Neuropathic Symptom Score (NSS), the Douleur Neuropathique en 4 Questions (DN4), the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) scale and the self-completed LANSS (S-LANSS). These questionnaires are already used in various studies of the prevalence of PDN. Jambart et al (6) used the DN4 questionnaire in the Middle East and reported that the highest prevalence of PDN was 53.7%. Erbas et al (12) used the LANSS questionnaire and reported a prevalence of PDN of 16% in the Turkish population with diabetes. Abbot et al (7) used the NSS questionnaire and observed a 21% prevalence in the population with diabetes the United Kingdom. S-LANSS is a self-completed version of LANSS. Bennett et al (13) compared an S-LANSS postal survey with an interview format and found that the S-LANSS scale correctly identified 75% of pain types when self-completed and 80% when used in the interview format. These findings support the S-LANSS scale as a valid and reliable self-report instrument for identifying neuropathic pain and that it is also acceptable for use in postal-survey research. Several studies used the S-LANSS questionnaire to diagnose neuropathic pain, including PDN (14–16). Liberman et al used the S-LANSS questionnaire and observed a 46.5% prevalence of PDN in the Israeli population with diabetes (17). Younis et al used S-LANSS to confirm the presence of neuropathic discomfort in patients with diabetic foot ulcers (14).

The S-LANSS questionnaire is based on self-assessment by the patient. It does not require healthcare professional input and examination to complete the questionnaire. It is a validated tool

that is easy to use, and data can be collected easily via post from the targeted population. It is routinely used in DN clinics. In contrast, the NSS questionnaire used by Abbot et al in a prevalence study of PDN in 10,000 patients needed assessment and examination by the healthcare professionals to complete the questionnaire (7). In comparison to the NSS questionnaire, the S-LANSS questionnaire is easy to use, the patients can complete the questionnaire by themselves and it can be used in a postal survey. However, completion of the S-LANSS relies on patients' understanding of the questions and their assessments. We used the S-LANSS questionnaire in this study because it is easy to conduct and is a validated tool to use in a postal survey (13).

The main aim of this study was to assess the feasibility of diagnosing PDN using a postal self-administered S-LANSS questionnaire (Appendix). Second, it compared the prevalence of PDN in subjects attending diabetes clinics in primary care and secondary care, respectively.

## Subjects and Methods

Primary care subjects were identified from the general practice database with the diagnosis of diabetes at Aston Healthcare, Whiston, Merseyside, United Kingdom. Secondary-care subjects were identified in the Diabetes Alliance for Research in England (DARE) database at Lancashire Teaching Hospitals NHS Trust (18). Patients younger than 16 and older than 80 years of age were excluded. All patients were sent by post a modified S-LANSS questionnaire, an information leaflet and a consent form for participation and for access to their blood results along with self-addressed return envelopes. In the modified S-LANSS questionnaire, a score of 12 or higher and bilateral stockings or stockings and gloves distribution of pain in the human figure were the criteria for the diagnosis of PDN in this study. The laboratory data and medical records held at Lancashire hospitals NHS Trust and Aston Health Care, Whiston, were used for this study. Ethical approval was granted by the National Research Ethics Service, United Kingdom, and institutional approvals were obtained from Lancashire Hospitals NHS Trust and Aston Health Care, Whiston, and the University of Central Lancashire.

## Statistical analysis

Data were analyzed using GraphPad Software (San Diego, CA) (19). The continuous variables were normally distributed and are expressed as means,  $\pm$  standard deviation (SD), median, 95% confidence intervals (CIs) and p values. The means were analyzed by unpaired Student t test. Categorical data were expressed as frequency distribution, percentage of subjects and groups and p values. The categorical data were also analyzed by a  $2 \times 2$  table using the Fischer exact test. The continuous variable descriptive statistics and trends in groups were calculated by the chi-square test using Minitab (State College, Pennsylvania, United States) statistical software (20).

## Results

A total of 205 patients with diabetes were identified from primary care and 266 from secondary care and were sent the prepaid postal questionnaire. A total of 204 (43.3%) subjects returned the postal modified S-LANSS questionnaire with the signed consent

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