The impact of painful diabetic neuropathy on quality of life: An observational study

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Article points

1. Painful diabetic neuropathy (PDN) is a common and potentially very serious complication of diabetes.
2. There is relatively little research aimed at quantifying the impact of PDN on quality of life (QoL) and mental health.
3. Here the authors report data from north-west England hinting that PDN is associated with a negative impact on QoL and anxiety.

Key words

- Anxiety
- Depression
- Painful diabetic neuropathy
- Quality of life

Authors

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About a third of people with diabetes experience painful diabetic neuropathy (PDN) at some point in their lives, and it is a distressing condition affecting individuals both physically and emotionally. The aim of the study reported here was to assess quality of life, anxiety and depression in people with PDN using the 36-item Short Form Health Survey and the Hospital Anxiety and Depression Scale questionnaires, comparing these results against those in with people with diabetes who did not have PDN. The findings are presented in this article.

Currently, over 380 million people worldwide are living with diabetes and it is estimated that this figure will rise to 592 million in the year 2035 (International Diabetes Federation, 2013). The prevalence of diabetes-related complications is also rising. Painful diabetic neuropathy (PDN) is a common complication of diabetes, affecting about a third of all people with diabetes (Tesfaye, 2009). It is characterised by bilateral symmetrical distal neuropathic pain in the lower extremities with varied symptoms including mild pins and needles, a tingling sensation, a shooting pain similar to electric shock, a constant burning sensation with nocturnal exacerbation, and contact hyper-sensitivity (allodynia; Larsen et al, 2002). Relentless pain and allodynia can affect people both physically and mentally and can cause disturbance in sleep, low mood, impotence and social withdrawal. In some extreme cases, the affected individual is unable to walk (Quattrini and Tesfaye, 1996; Galer et al, 2000; Gardner and Shoback, 2007). PDN can significantly alter – and, moreover, has a huge impact on – individuals' quality of life (QoL).

Currently, there are only a few studies that have been performed specifically to measure the physical and mental impact of PDN on QoL. The study reported here was designed to assess QoL, anxiety and depression in people with PDN (PDN group) compared with those with diabetes not known to have PDN (control group).

There are several health-related questionnaires available to assess QoL and physical and mental wellbeing (Healthmeasurement.org, 2014). Typically, researchers use the 36-item Short Form Health Survey (SF-36®) for the assessment of QoL and the Hospital Anxiety and Depression Scale (HADS) for the assessment of mood and anxiety. Ware and Sherbourne (1992) introduced SF-36, which was designed for use in clinical practice and research, health policy evaluations and general population surveys. SF-36 includes 36 subjective questions that assess eight health concepts of QoL from the patient's point of view:

1 Limitations in physical activities because of health problems.
2 Limitations in social activities because of physical or emotional problems.
3 Limitations in usual role activities because of physical health problems.
4 Bodily pain.
5 General mental health (psychological distress and wellbeing).
6 Limitations in usual role activities because of emotional problems.
7 Vitality (energy and fatigue).
8 General health perceptions.

SF-36 is a practical, reliable and valid measure of physical and mental health and has been

used in a variety of chronic health conditions including diabetic neuropathic pain (Garratt, 1993; Ware et al, 1994; Rosenstock et al, 2004; Vinik et al, 2013) and published in more than 4000 documents, as of 2002 (Turner-Bowker et al, 2002).

The HADS questionnaire was originally developed by Zigmond and Snaith (1983) for psychometric evaluation. Since then, it has been widely used worldwide by health professionals, in both the community and hospital settings, and it has been found to be both a reliable and a valid measure of anxiety and depression (el-Rufaie and Absood, 1987; Nortvedt et al, 2006). The HADS questionnaire is based on a total of 14 questions, seven for anxiety assessment and seven for depression. HADS provides clear cut-off scores for severity of anxiety and depression. We felt that HADS would serve as an ideal tool for screening and thus adopted it in our study.

Methods

Study design

This was an observational study. The SF-36 and HADS questionnaires were used for data collection, based on the rationale described above. It takes approximately 15 minutes to fill in the SF-36 questionnaire and 5 minutes to fill in the HADS questionnaire, which meant that participants were able to fill these in while waiting for their appointment or to post them back to the research team after completing them at home.

Participants

The PDN group was formed from attendees at the diabetic neuropathic pain clinic at Chorley and South Ribble District General Hospital, while the control group (comprising people with diabetes not known to have neuropathic pain) was formed from individuals visiting the Aston Healthcare GP surgery at Whiston (Merseyside) for diabetes review. Each group consisted of 25 consecutive consenting patients at the respective sites. Individuals under 16 or over 80 years of age were excluded from participation. All individuals gave consent for participation. Institutional approvals were obtained at both centres for the study.

Assessment of QoL, anxiety and depression

SF-36 (used for QoL assessment)

The SF-36 questions were scored from 0 (worst possible functioning) to 100 (highest level of function). The average scores from those questions that addressed each specific area of a functional health domain provided the final score for the domain. Aggregate scores were compiled as a percentage of the total points possible, using the RAND scoring system (RAND Health, 2014).

Of the eight domains (described earlier), four relate to physical health (physical functioning, physical health limitation, pain and general health) and four to mental health (social functioning, emotional wellbeing, fatigue and emotional problem limitation). Aggregate scores for physical health domains and for mental health domains were also calculated.

HADS questionnaire (used for the assessment of anxiety and depression)

Each HADS question was scored from 0 (excellent mental health) to 3 (worst mental health). Aggregate scores (with a maximum of 21) were calculated for the seven anxiety questions and the seven depression questions. Scores between 0 to 7 were considered "normal", for both anxiety and depression assessment. Scores of 8 and above were considered to be significant for the diagnosis of anxiety or depression (el-Rufaie and Absood, 1987; Nortvedt et al, 2006).

Statistical analysis

Data were analysed using GraphPad software (GraphPad Software Inc, 2014). For the normally distributed continuous variables from SF-36 and HADS, means (± standard deviation [SD]) were calculated and analysed using the unpaired Student's *t*-test. Categorical data were also calculated, as a percentage of participants. The categorical data from HADS were analysed as a 2x2 table using Fisher's exact test.

For the purpose of visually summarising the data, box-plots were also created, using Minitab (2014) statistical software, and these represented median, minimum and maximum values, as well as the lower and upper quartiles.

Page points

1. In this observational study, the 36-item Short Form Health Survey was used for the assessment of quality, while the Hospital Anxiety and Depression Scale was employed to explore specific aspects of mental health.
2. The painful diabetic neuropathy group was formed from attendees at the diabetic neuropathic pain clinic at Chorley and South Ribble District General Hospital, while the control group (comprising people with diabetes not known to have neuropathic pain) was formed from individuals visiting the Aston Healthcare GP surgery at Whiston (Merseyside) for diabetes review.
3. Each group consisted of 25 consecutive consenting patients at the respective sites.

Page points

1. Few studies have specifically reported the impact of painful diabetic neuropathy (PDN) on quality of life (QoL) and psychological wellbeing of people with diabetes
2. The authors' data hint at an association of PDN with poor QoL and anxiety symptoms.

Table 1. Data for the eight domains of the 36-item Short Form Health Survey (SF-36®) in the study groups.

SF-36 domain	Mean score in PDN group	Mean score in control group	*P*-value
Physical functioning	28.4	65.2	<0.0001*
Physical health limitation	17.0	61.0	<0.0002*
Pain	29.3	59.9	<0.0005*
General health	31.1	52.0	0.0034*
Social functioning	48.8	68.0	0.0292*
Emotional wellbeing	61.4	69.3	0.292
Fatigue	25.4	42.4	0.0073*
Emotional problem limitation	41.3	72.0	0.0188*

*$P<0.05$.
PDN=painful diabetic neuropathy.

Results

The two groups were similarly distributed ($P>0.05$) in age and also in sex (PDN group, 60% male; control group, 56% male). Participants in the PDN group had significantly ($P<0.05$) lower scores in seven out of eight domains of SF-36 compared with the control group (*Table 1*). The exception was emotional wellbeing. Both physical health and mental health summary scores were significantly lower in the PDN group than the control group (*Figure 1*).

Individuals in the PDN group had significantly higher HADS anxiety scores, but HADS depression scores were not statistically significantly different from those in the control group (*Figure 2*).

Fourteen individuals (56%) out of 25 had anxiety in the PDN group (the mean score was 7.32 ± 3.42). In the control group, five individuals (20%) met the criterion for a diagnosis of anxiety (the mean score was 4.72 ± 4.34). The *P*-values calculated from comparisons of the continuous data and of the categorical data were 0.023 and 0.018, respectively (both statistically significant).

Fifteen people (60%) out of 25 had depression in PDN group (the mean score was 8.36 ± 4.05). In the control group, 11 people (44%) met the criterion for a diagnosis of depression (the mean score was 6.6 ± 4.16). The *P*-values calculated from comparisons of the continuous data and of the categorical data were 0.136 and 0.396, respectively (neither being statistically significant).

Discussion

Few studies have specifically reported the impact of PDN on QoL and psychological wellbeing of people with diabetes (Quattrini and Tesfaye, 1996; Benbow et al, 1998; Galer et al, 2000; Gore et al, 2005; Argoff et al, 2006; Van Acker et al, 2009). Our data reveal a significant association of PDN with poor QoL and anxiety symptoms but not with depression. This last observation could be because a number of people with PDN were treated with antidepressants for their neuropathic pain, and the underlying symptoms of depression might have thus been reduced to some extent, or it could be down to insufficient power.

Comparison with existing data

The data from our study hint at a significant impairment of QoL associated with PDN within both the physical and mental health areas of the SF-36 questionnaire. The results are consistent with similar research reported using a shorter (12-item) version of the questionnaire. Van Acker et al (2009) found significant impairment in both the physical and mental health components of QoL. In another study, by Benbow et al (1998), the Nottingham Health Profile questionnaire was used, and it was found that there were significant impairments in QoL in five of the six domains (emotional reaction, energy, pain, physical mobility and sleep). The exception was the social isolation domain. Similarly, in the present study, the data showed significant impairment in all of the domains but one (emotional wellbeing).

As mentioned earlier, there are reports of severe PDN with constant unrelenting neuropathic pain, disturbance of sleep and even the loss of the ability to walk, owing to the severity of pain (Quattrini and Tesfaye, 1996; Galer et al, 2000; Gardner and Shoback, 2007). This can in turn lead to withdrawal from routine activity of life, including employment, and can also affect emotional wellbeing and contribute to social isolation. The data for the emotional wellbeing domain in our study and the social isolation domain of Benbow et al (2000) study were not significant, perhaps owing to the presence of only a small number of the severe type of PDN case associated with extreme symptoms.

HADS data in the present study showed that more than half (56%) of the participants in the PDN group had anxiety symptoms, with this proportion (and the summarised continuous data) being statistically significantly different from those of the control group. The data were broadly consistent with those reported by Gore et al (2005), using the HADS questionnaire. They reported that 35% of their participants had anxiety symptoms. However, they used a threshold score on HADS of 11 or above (moderate-to-severe symptoms), while we used a threshold score of 8 and above. Our data for depression symptoms showed that more than half (60%) of the individuals in the PDN group had symptoms of depression (a score above 7). However, comparisons of the differences from the control group were not statistically significant. In contrast, Gore et al (2005) showed a significant association between PDN and depression. In their study, the prevalence of depression in people with PDN was 28% (a score of 11 or above).

A large systematic review and meta-analysis reported the prevalence of depression in people with diabetes to be around 17.5% (Ali et al, 2006). In our study, the control group of people with diabetes was found to have an unusually high prevalence of depression (44%). This may be down to random factors or could have resulted from the control group having been taken from an area of relatively low socioeconomic status.

Strengths and limitations of the study

The study population was well defined, and both groups of participants had a 100% response in completing the two questionnaires. The groups were similar in age and in the ratio of males to females.

Recall bias could potentially exist when participants are completing questionnaire. However, most questions from both questionnaires used were based on current or recent physical and mental wellbeing of the person, and hence recall bias is considered to have been minimal.

A major limitation of the study relates to the selection of the control group. As mentioned

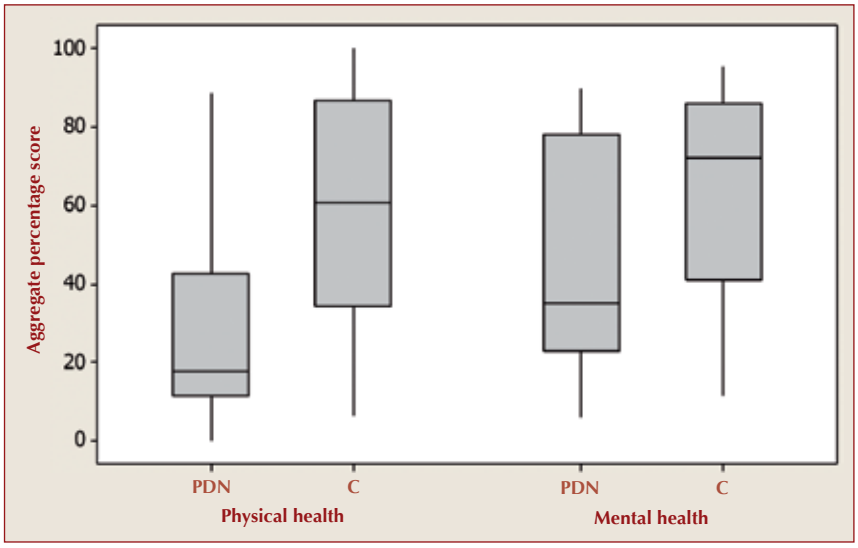

Figure 1. A box-plot of the overall physical and mental health scores from the 36-item Short Form Health Survey in the painful diabetic neuropathy (PDN) and control (C) groups (boxes for median and lower and upper quartile values [with bars for minimum and maximum score]; n=25).

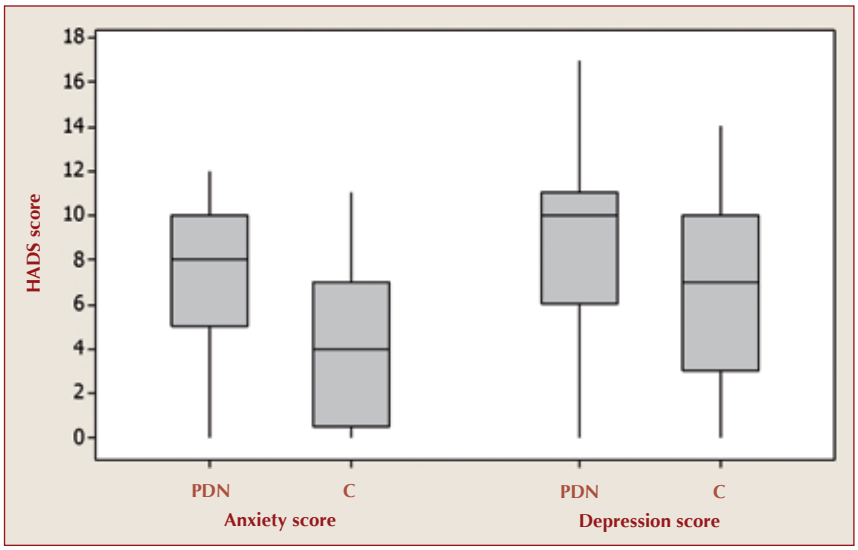

Figure 2. A box-plot of the Hospital Anxiety and Depression Scale (HADS) scores in the painful diabetic neuropathy (PDN) and control (C) groups (boxes for median and lower and upper quartile values [with bars for minimum and maximum score]; n=25).

above, the GP surgery from which the control group data were taken lies in an area of north-west England with a low socioeconomic status. It is known that low socioeconomic community status has a positive association with prevalence of depression (Murali and Oyebode, 2004). Furthermore, the two groups were selected from healthcare settings of a different nature. These discrepancies, and the lack of randomisation in the study, could thus have led to selection bias, which in turn could have had an impact on outcomes. Data were not collected to compare factors other than age and sex (duration of diabetes and the presence of other complications are among the potential confounding factors). As with any non-randomised study, it is not possible to infer a causal relationship and thus our conclusions can only be tentative at best.

Conclusion

Overall, we believe our study tentatively suggests that, in a population in north-west England, PDN has a clinically significant impact on QoL and is also associated with symptoms of anxiety. Further research would be needed to shed more light on depression and to draw firmer conclusions on the potential causal nature of the association observed.

In light of our findings, we suggest that, when caring for people with PDN, clinicians should consider exploring psychosocial wellbeing and the overall impact of the condition on QoL. ■

Declaration of competing interests

The authors reported no conflict of interests regarding the publication of this paper.

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"When caring for people with painful diabetic neuropathy, clinicians should consider exploring psychosocial wellbeing and the overall impact of the condition on quality of life."