The Neuropathic Pain Scale and its reliability and validity for diabetic neuropathy

Pain is a subjective experience and as such is difficult to assess objectively. The common method of assessment is to use a pain scale so that patients can rate different aspects of their experience of pain. Neuropathic pain, which is caused by a dysfunction of the nervous system and is often associated with the diabetic foot, can be assessed using the Neuropathic Pain Scale. This article reviews the literature for the Neuropathic Pain Scale to assess its reliability and validity in identifying levels of neuropathic pain. The authors conclude that the NPS is a valid and reliable tool.

Pain is a sensation that the majority of us will have experienced in varying degrees throughout our lives. Various definitions of pain have been used over the years. In 1986, the International Association for the Study of Pain (IASP) described it as:

“an unpleasant sensory or emotional experience associated with actual or perceived tissue damage or expressed in terms of such damage.”

In Bonica’s Management of Pain, it is argued that the IASP should have included definitions of acute, chronic, recurrent and cancer pain. In 2008, the World Union of Wound Healing Societies (WUWHS) defined wound pain as:

“a noxious symptom or unpleasant experience directly related to an open skin ulcer.”

Wound pain may arise from various wound aetiologies, such as the diabetic foot, pressure ulcers and arterial and venous leg ulcers. Acute pain is temporally related to injury. It is felt instantly, it is localised, and it is often described as a sharp, pinprick type of pain which eventually subsides as the wound heals. In contrast, chronic pain is background pain that is persistent at rest and between wound-related procedures, and extends for more than three months or lasting longer than a wound that is healing on a normal trajectory.

Pain is multidimensional, experienced by an individual and not only involves physical sensation, but also has a psychological impact. Mood, personality, coping style, the degree of preparation, uncertainty, control over the pain, past experience of pain, and social and religious influences are various psychological and social factors that can affect an individual’s ability to cope with pain. Carr highlighted the presence of bias among healthcare professionals in their assessment of pain based on their expectations of how certain individuals should cope with pain. He concluded that the experience of pain is influenced by age, past experience of pain, gender, and culture, therefore, all need to be considered while planning for appropriate and effective care. However, pain and suffering are private, internal events that cannot be directly and empirically observed by clinicians, or assessed via blood tests or X-rays, and as expressed by McCaffery:

“pain is what the experiencing individual tells you it is and exists when he/she says it does.”

In order to understand pain, communication between the patient and the clinician is mandatory. This may help to achieve a correct diagnosis and determine the intensity, quality and duration of pain, as well as evaluating the effectiveness of pain therapy. Therefore, the assessment of pain requires a psychosocial, behavioural and organic approach, which encompasses not only the severity of pain and related pathology, but...
also of the individual\(^{[17]}\). Failure to assess wound pain may lead to significant distress for the patient\(^{[19]}\).

Pain assessment tools are generally simple to use, efficient and minimally intrusive and are used primarily for acute pain management in hospital settings. They include: verbal rating scales (VRS), numerical rating scales (NRS), and visual analogue scales (VAS)\(^{[16]}\). The NRS asks the patient to rate their pain from 0 to 10 (11 point-scale) or from 0 to 100 (101-point scale), with 0 equal to no pain and 10 or 100 equal to the worst possible pain. NRSs are valid, reliable, easy to administer and score, and include the Brief Pain Inventory (BPI)\(^{[20]}\), LANNS Pain Scale\(^{[20]}\) and the Neuropathic Pain Scale (NPS)\(^{[21,22]}\). This article will consider the NPS in detail using a literature review to identify studies that have evaluated its effectiveness.

### The Neuropathic Pain Scale

The IASP defines neuropathic pain (NP) as:

“pain initiated or caused by a primary lesion or dysfunction of the nervous system”

and it is a group of neurological disorders characterised by chronic pain and typically includes reports of burning, hyperpathia, and lancinating pain regardless of aetiology\(^{[23]}\). Peripheral neuropathy is one of the most common complications of diabetes, and is associated with long standing peripheral neuropathic pain affecting the life of a patients with diabetic foot. The NPS was developed by Galer and Jensen in 1996\(^{[21]}\) to assess NP based on their clinical experience of identifying the most frequent words used by patients with NP to describe their pain. The NPS includes two descriptors of pain including intensity and unpleasantness, that have previously been identified as global descriptors of pain\(^{[24,25]}\), and eight descriptors that assess specific qualities of NP: sharp, hot, dull, cold, sensitive, itchy, deep and surface pain. Each of these 10 dimensions has a 0 to 10 NRS, in which 0 is equal to no pain and 10 equals the most intense pain.

### Psychometrics and clinimetrics

Psychometrics or clinimetrics is the process of scientific development and evaluation of an evidence-based clinical assessment tool, which assesses the accuracy, internal consistency, reliability, and validity of a tool\(^{[26–28]}\). Although both terms have been used in the medical literature search, the majority of new developments in scale construction like new variations of the intraclass correlation, item response theory, structural equation modeling, and cognitive theories are reported in the psychometric literature, so continued use of clinimetrics not only leads to confusion and misunderstanding, but cuts the scale developer off from a long, rich, and flourishing literature\(^{[29]}\). Hence Streiner has questioned the use of the term clinimetrics and suggests that the term psychometrics might be more useful\(^{[29]}\).

### Literature review

#### Validity

Validity of a measured tool determines whether the tool truly measures what it claims to measure\(^{[30,31]}\), and it may be achieved by various means, such as by how the test measures what it is meant to measure (content validity), by asking the opinion of an expert group (face validity), by comparing it with results of other established pain assessment scales (concurrent validity), by considering whether it is able to predict pain-related outcomes (predictive validity) or by questioning whether a test designed to measure a construct described by a theory really measures this construct (construct validity)\(^{[32]}\).

There are a number of aspects of the NPS design that suggest it is a valid tool. In 1996, Galer and Jensen\(^{[21]}\) enrolled 288 consecutive patients with one of four NP conditions: post-herpetic neuralgia (PHN), reflex sympathetic dystrophy (RSD), traumatic peripheral nerve injury (TPNI), and diabetic neuropathy (DN). The authors evaluated the predictive validity of the NPS, using analysis of variance (ANOVA) for each of the 10 descriptors. The authors concluded that the NPS descriptors were able to distinguish PHN from RSD, TPNI, and DN, with PHN being described as more sharp (F=5.74; \(P<0.01\)), more sensitive (F=12.63; \(P<0.01\)), more itchy (F=14.07; \(P<0.01\)), and less cold (F=21.36; \(P<0.01\)).

In a randomised controlled trial by Jensen et al\(^{[22]}\), 159 patients with diabetes-related foot pain were randomly assigned to receive opioid (controlled-released oxycodone) or placebo for six weeks. NPS was administered before, during, and after study treatment. The analysis

“Mood, personality, coping style, the degree of preparation, uncertainty, control over the pain, past experience of pain, and social and religious influences are various psychological and social factors that can affect an individual’s ability to cope with pain.”

\(^{[30–32]}\)
Reliability

Reliability is an important measure in assessing the accuracy of NPS and refers to an assessment of error measurement, which means that the test is likely to give the same results on repeated occasions [34]. The reliability is calculated using the intra-class correlation coefficient (ICC) [37]. The values for reliability coefficients range from 0 to 1.0. A coefficient of 0 means no reliability and 1.0 means perfect reliability. Since all tests have some error, reliability coefficients never reach 1.0. Generally, if the reliability of a standardised test is above 0.80, it is said to have very good reliability; if it were below 0.50, it would not be considered a very reliable test [38]. Therefore, the minimum acceptable value for reliability is set to 0.70 [39].

The reliability of NPS came from a sub-study by Rog et al. [35] who administered NPS to 36 patients with MS together with SFMPQ, HADS, and SF-36. The authors tested the short-term test or re-test reliability by providing NPS to the patients at home by post after telephone calls, or in the clinic or the day-case ward. For the long-term test or re-test reliability, NPS was posted to all those patients approximately three weeks after the initial completion of questionnaires. This included a written reminder to answer questionnaires solely for the pain identified at initial completion. In the test or re-test analysis only those patients whose pain remained the same were included. In the short-term test re-test reliability 45% initially completed the NPS at home, 25% in clinic, and 2% on the day-case ward, demonstrating good agreement of pain remained the same were included. In the short-term test re-test reliability, NPS was posted to all those patients who had completed the NPS at home, 25% in clinic, and 2% on the day-case ward. For the long-term test re-test reliability, 90% repeat NPSs were completed and returned. The ICC for the individual NPS items varied between 0.45 and 0.78, with overall ICC for the total NPS score being 0.71, just above the acceptable value of 0.7, showing the reliability of the NPS tool.

Sensitivity is defined as the proportion of the people with disease who have a positive test result, and specificity is the proportion of people without disease who have a negative test result [40]. The NPS needs to be sensitive, specific, and reliable to changes in the pain experience over time. Galer and Jensen [41] tested the psychometric properties of the NPS using intravenous lidocaine and phenolamine infusion on a total of 78 patients.

To determine the sensitivity of the NPS descriptors to treatment, a series of repeated measures of...
ANOVA were performed with treatment (lidocaine versus phentolamine) and time (immediately before versus immediately post-treatment) as the independent variables, and responses to each of the NPS descriptors as the dependable variables. The authors concluded that two treatments were effective, on average, for reducing pain, with most pain qualities decreasing post-treatment. Lidocaine was found to be particularly effective for unpleasant and deep qualities of pain, whereas lidocaine and phentolamine were similarly effective for the remaining qualities of NP. Moreover, the authors did mention the limitations of their second study in generalising the results, as the study was not performed in a randomised, double-blind fashion rather the study was done to assess the ability of the NPS to detect the treatment effect, not to assess the efficacy of the therapies.

The study by Galer and Jensen[21] not only indicates high sensitivity and specificity of the NPS, but also suggests discriminant validity (an ability for changes to individual dimensions to reflect specific pain treatments and provide evidence of their distinct value). Jensen et al[22] studied the use of the lidocaine patch 5% in patients with peripheral NP, lower back pain (LBP), and osteoarthritis with exception of cold pain in the LBP group. Each of the NPS descriptors showed significant change after using a lidocaine patch with relative larger changes in intensity, unpleasantness, sharp and deep pain, and relatively smaller changes in cold, sensitive and itchy pain. The results support the potential use of the NPS for assessing the patterns of changes in pain qualities that can be observed after treatment for pain. Similarly, Galer et al[23] deployed the NPS as the only pain assessment tool specifically designed to measure the distinct components of NP, and Argoff et al[24], studied the impact of the lidocaine patch 5% on pain associated with PHN, DN and LBP. Both studies demonstrated the improved sensitivity and reliability of the NPS in differentiating various pain states and also in assessing the treatment outcomes for various pain qualities associated with given pain states. However, in contrast, Lynch et al[25] showed adenosine affecting only five of the NPS descriptors, suggesting that it has a different treatment mechanism.

The overall usability is important for any screening tool and to become accepted it needs to save users’ time and offer practicality, resulting in better patient care and cost savings. For the readability and clarity of the tools, it is important that users are able to easily understand, interpret and comprehend the questionnaire in order to self-administer the tool. Galer and Jensen[26] and Jensen et al[42] addressed these concerns and provided explanations and instructions, prompting the patients to note that pain can have many different qualities and then asked them to rate their pain according to 10 descriptors of NPS. However, Backonja and Stacy[27] argued against this by showing that in the results from the NPS and Neuropathic Pain Questionnaire (NPQ)[48], the burning pain from NPQ and hot pain from NPS were essentially the same feeling of hot and burning, but the frequency and severity of these two descriptors were different.

Conclusion
Screening tools should be easy and quick to perform, acceptable to the patients and healthcare workers, and have good reproducibility and validity (Stratton et al, 2004). Precision is necessary, as patients who are in pain may not want to spend time, possibly in an uncomfortable position, completing lengthy charts or questionnaires. However, diagnostic tests are seldom 100% accurate and both false positive and false negative results can occur.[49]

The NPS is the first pain measure designed specifically for NP. It assesses various qualities of NP and has sensitivity and specificity in relation to NP[21,42,43]. Its short-term test/re-test and long-term test/re-test reliabilities have been demonstrated by Rog et al[45] in a study of patients with MS. They demonstrated that the NPS could discriminate between different categories of NP, and that NPS scores changed in response to various treatments. However, the NPS cannot discriminate NP from non-NP, and its ability to do so remains untested[46].

The literature search has shown that the NPS is a valid and reliable tool. It captures a large proportion of the patient’s own description of their NP and it is largely free from ambiguity. It can be administered both by post and in hospital, and it shows both convergent and discriminant validity with other commonly-used scales[47]. Thus it is evident that the NPS is sensitive and specific to the neuropathic pain experience in the clinical setting, demonstrating a range of psychometric principles.
“Precision is necessary, as patients who are in pain may not want to spend time, possibly in an uncomfortable position, completing lengthy charts or questionnaires.”