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Chronic diabetic peripheral neuropathic pain: psychometric properties of pain and physical function outcome measures

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ABSTRACT

Background: Diabetic peripheral neuropathy (DPN) not only produces severe pain, tingling, and numbness sensation in the involved limbs, but also limits physical function due to loss of sensation. There are no recommended methods for clinical situations to measure these signs and symptoms. Studies with high methodological quality use the modified Brief Pain Inventory for Diabetic Peripheral Neuropathic pain (mBPI-DPN) scale and the short form Screening of Activity Limitations and Safety Awareness (sSALSA) scale for measuring these symptoms in DPN population. In order to capture a real change in the variables of interest, the psychometric properties of that measure should be within acceptable limits. As these two measures were not assessed for all of the psychometric properties, there was a need for further evaluation.

Methods: Data were collected ($n=38$ patients) in a longitudinal cohort study. Test–retest reliability (0–4 weeks) and Responsiveness- Minimal Clinically Important Difference (MCID) (0–12 weeks) were calculated between two sessions. Convergent validity was assessed (between mBPI-DPN pain interference and sSALSA scale).

Results: Both measures demonstrated acceptable test–retest reliability (mBPI-DPN scale: ICC = 0.61, SEM = 12.92; the sSALSA scale: ICC = 0.81, SEM = 4.88) and convergent validity (Spearman's correlation coefficient $r=0.62$). The computational methods used in different methodologies to calculate MCID for the mBPI-DPN and the sSALSA scale were varied, hence the magnitude of derived MCID scores also varied.

Conclusions: Our study have provided evidence to add to the scientific basis surrounding the use of mBPI-DPN and sSALSA scales in DPN population, but standardization of these measures in a larger population is required

KEYWORDS

Diabetic neuropathic pain; physical functions; reliability; validity; responsiveness

TRIAL REGISTRATION

Australian New Zealand Clinical Trials Registry ACTRN12613000748718.

1. Introduction

Neuropathic Pain (NeP) is defined as ‘pain initiated or caused by a primary lesion or dysfunction in the nervous system’ by the Assessment Committee of the Neuropathic Pain Special Interest Group (NeuPSIG) of the International Association for the Study of Pain (IASP) [1]. The main causes of NeP vary globally [2]. In developing countries, infectious diseases such as Human Immunodeficiency Virus [3] and leprosy [4], trauma (due to war wounds and amputations) [5] and radiculopathies related to spinal column disease [2] are among the most common causes of NeP. In developed countries, diabetes is considered to be one of the most common causes of NeP [6].

According to the Centres for Disease Control (2011), approximately 26 million American adults and children are currently affected with diabetes mellitus, and 60–80% of this population is expected to develop neuropathy in their life time [7]. Diabetes induced neuropathy, also known as diabetic peripheral neuropathy (DPN), [8] is defined as ‘pain arising as a direct consequence of abnormalities in the peripheral somatosensory system in people with diabetes’ (IASP) [1,9]. For those with DPN, pain is considered a risk factor for, as well as a cause of, disability.

A range of pain assessment guidelines have been developed including the Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT) [10] along with assessment guidelines

from the European Federation of Neurological Sciences (EFNS) [11], and the NeuPSIG [12]. These guidelines recommend outcome measures (OMs) that evaluate a range of issues associated with NeP, spanning six domains: 'Pain', 'Physical functioning', 'Emotional functioning', 'Participants' rating of overall improvement', 'Participants' satisfaction with treatment and symptoms', and 'Adverse events' [13]. In chronic pain conditions, as pain increases it becomes disruptive to many aspects of a person's life [14,15]. Along with assessment of pain relief, assessment of improvement in functional deficits should always be assessed in these cases, as patients tend to correlate their recovery with their ability to perform their normal household physical functions, that is, their day to day activities.

The choice of which OM to use may be based on the study group, the purpose of the questionnaire, its psychometric properties as shown by reliability, validity, and responsiveness, and on practical considerations (for example, ease of scoring and how long it takes to complete) [16,17]. The usefulness of measurement in clinical research and decision-making depends on the extent to which clinicians or researchers can rely on data as accurate and meaningful indicators of behavior or attribute. In order to be confident about the output of a measure, the psychometric properties of that particular measure should be made available [18]. Since a variety of OMs are available for the above-stated domains, the quality of the information provided by these measures depends, in part, on the psychometric properties of available OMs [19]. Thus knowledge about the psychometric properties of available OMs in published trials may provide a useful basis for selecting the best/most appropriate measurement instrument for a specific purpose.

The prevalence of NeP is expected to increase in coming years for a variety of reasons. First with an estimated increase in the aging population that there will be concurrent increase in the prevalence of NeP, which is more prevalent in the elderly. Second with the advancement of medical science, the survival rate of patients suffering from cancer, HIV infection, and diabetes, for example, has increased. These are known to be leading causes of the development of NeP [20,21]. Such factors will lead to increases in the numbers of people with NeP globally. These factors underscore the need for development of a common set of OMs to inform questions about treatment effectiveness. For this study, the tools to be evaluated assessing pain and physical functions were the modified Brief Pain Inventory (mBPI-DPN) scale, and the short form Screening of Activity Limitations and Safety Awareness (sSALSA) scale; these were chosen based

on their clinical relevance to diabetic participants (including their pain and physical function).

The mBPI-DPN is a modified form of the original BPI, a self-administered scale used in clinical pain trials to assess pain severity and its impact on activities of daily living [14]. The reliability of the modified BPI scale has been established in various language versions: a German chronic pain population [22], Spanish cancer-related pain [23], Taiwanese cancer-related pain [24], and in an English osteoarthritis population [25]. However, the reliability of the modified BPI scale in the English language in the DPN population has never been reported. The sSALSA scale covers activity areas such as mobility (feet), self-care, work (hands), and dexterity (hands). Fifteen of the 20 questions cover aspects of manual activities, while the remaining 5 concern activities that often imply problems for people with affected sensibility in other body areas. The sSALSA scale was developed for a population with neuropathy due to leprosy and diabetes [26]. However, a careful study of the literature revealed that the reliability and validity of this scale have been assessed only in a leprosy population; usage of the sSALSA scale for DPN has not been given great attention by researchers in the past and this motivated the present study. The sSALSA scale is the only scale which deals with the unique presentation of the DPN: that is, measuring the effect of loss of sensation on a person's ability to carry out activities without injuring themselves. Though the psychometric properties of these two OMs have been established in other populations, this is the first study to investigate their psychometric properties in a DPN population.

2. Study objectives

- Evaluate the relative and absolute reliability of the mBPI-DPN and sSALSA scale in a group of patients with chronic DPN.
- Determine the convergent validity for the mBPI-DPN pain-related interference and sSALSA scale in adults with DPN.
- Explore the responsiveness for pain and physical functioning OMs to determine the natural progression/variation of the DPN disease.

3. Methods

3.1. Design

This study was a prospective, longitudinal cohort study. Approvals were obtained from the University of Otago Human Ethics Committee (Health): reference number H13/041 and Maori Research Consultation through the Ngāi Tahu Research Committee; all participants signed an informed consent form. The study protocol has been previously

reported [27]. Participants were recruited from New Zealand (North and South Island) via advertisements on community boards, and in local newspapers. Invitation letters, along with information sheets, were sent to the general physicians (GPs) in the Otago region for referral of potential participants to this study. Invitation letters and information sheets were also sent to 15 branches of Diabetes NZ situated throughout the New Zealand (North Island: Auckland, Tauranga, Rotorua, Hamilton, Gisborne, New Plymouth, Napier, Palmerston North, and Wellington; and in the South Island: Nelson, Christchurch, Timaru, Oamaru, Dunedin, and Invercargill). A snowball sampling technique (Exponential non-discriminative) as a chain referral was also followed [28]. All interested volunteers were requested to contact the clinical research administrator (CRA), at the Centre for Health Activity and Rehabilitation Research (CHARR), University of Otago, telephonically or via electronic mail. The CRA then approached the volunteers (by telephone) and screened for eligibility. Participants who scored ≥ 12 on S-LANSS, suggestive of pain of a predominantly nerve origin, were eligible to participate in the study [29]. The S-LANSS is a screening tool which has been recommended by the EFNS to distinguish pain of neuro-pathic origin, from non-neuropathic sources [11].

3.2. Participants

Inclusion criteria: Adults (18 years and over) with a confirmed diagnosis of diabetes given by a GP, associated with chronic (≥ 3 months) NeP [30] and a score of ≥ 12 on the S-LANSS were included in the study. Exclusion criteria: Participants who are unable to comprehend and record OM data were excluded.

3.3. Questionnaires

3.3.1. Pain outcome measure: the modified brief pain inventory-diabetic peripheral neuropathy item and scale score

The mBPI-DPN is a modified form of the BPI, a self-administered scale used in clinical pain trials to assess pain severity and its impact on activities of daily living [14]. It is a numeric rating scale, which includes a four-item pain severity scale, and a seven-item pain interference scale. Each BPI item uses a 0–10 rating anchored at zero for ‘no pain’ and 10 for ‘pain as bad as you can imagine’ for severity, and a 0–10 scale to measure interference from 0 ‘does not interfere’ to 10 ‘completely interferes’. Total scores range from 0 to 110, with higher scores indicating more pain, and pain-related interference in general activities, mood, walking ability,

normal work, relations with others, sleep, and enjoyment of life.

3.3.2. Physical functional outcome measure: short form for screening of activity limitation and safety awareness scale

The sSALSA is a modified form of the original 374 item scale, consisting of 19 different sections, including self-care, around the house, reading and writing, getting around, leisure, child care, and working with tools. The original SALSA and the sSALSA scale are optimally interview-based instruments, where items in the scale are closed, with structured questions. The questions reported in the scale should be asked exactly as they are written. The literature supports that the sSALSA scale can be administered by any literate medical or non-medical worker/volunteer [31]. Since this study was conducted in a developed country (New Zealand) where all the potential participants were expected to be literate, and one of the inclusion criteria for this study was to be able to understand English, the sSALSA scale was administered as a self-reported OM. Since the mode of administration of the scale was changed to a self-report measure, a Question-by-Question Guide was provided along with the sSALSA scale (as originally developed to be used by the interviewers to accompany the scale), for the participants to understand the underlying meaning of the individual questions [26]. For the purpose of grading, participants were asked to report whether a particular activity was ever carried out by them. If the response was NO, then they were instructed to grade the item as zero. However, if the response was YES, grading was provided by asking further questions, such as: whether this activity was perceived as easy: Grade 1, a little difficult: Grade 2, or very difficult: Grade 3. Participants were instructed that if the activity was physically impossible or avoided because of a perceived risk of injury, they should report it as Grade 4, indicating an advanced degree of activity limitation.

3.3.3. Patient global impression of change scale

PGIC scale is a seven-point Likert scale that asks participants to rate their change of symptoms at the follow-up compared to baseline. The participant was instructed to write down their present chief complaint and asked to answer the following question, ‘Since beginning this study, how you would describe the change (if any) in Activity limitations, Symptoms, Emotions, and Overall Quality of Life, related to your painful condition?’ The PGIC has seven possible answers ranging from zero – ‘No change (or condition has got worse)’ to seven, indicating – ‘A great deal

better, and a considerable improvement that has made all the difference'. Participants were instructed to circle the number which matched most closely with their degree of change since participating in this study for the stated complaint [32].

3.4. Examination procedure

Data were collected at baseline, after a 4-week interval, and after a 12-week interval. All participants were asked to complete a baseline questionnaire, providing some sociodemographic information. Medication usage for controlling diabetes and nerve pain was recorded at baseline, and at week four, to monitor usage during the study. The Charlson Comorbidity Index was used to assess the presence of other associated illnesses [33,34]. Each participant was requested to complete two scales: mBPI-DPN and sSALSA scale at baseline assessment. On re-assessments, the same two scales (Pain OM: mBPI-DPN scale and Physical function OM: sSALSA scale) including the PGIC scale were sent with instructions to all participants (either electronically or by mail) for completion. The PGIC was used as an external criterion for the overall participant improvement at 12 weeks follow-up [32]. Participants were instructed to re-send their completed forms via e-mail/priority stamped enclosed envelopes to the CHARR within two weeks of receipt. To increase the response rate, modified Dillman's respondent contact strategies were adopted [35]. Under this strategy, if no response was received after two weeks, two follow-up reminders (telephonic call/e-mail) were made by the CRA.

4. Statistical analysis

Statistical analysis was performed with the IBM Statistical Package for Social Sciences (SPSS) version 22 (IBM Corporation, New York, NY, USA) for Windows. Descriptive statistics were used to summarize demographic characteristics of the DPN population. The means, 95% CI and standard deviation scores for the mBPI-DPN scale, and the sSALSA scale evaluated on three testing occasions (baseline, at 4-week interval, and at 12-week interval) were calculated.

4.1. Analysis for test-retest reliability

Intraclass Correlation Coefficient ($ICC_{2,1}$), and Standard Error of Measurement (SEM), and its percentage (SEM%), Smallest Real Difference (SRD), and its percentage (SRD%) were calculated to derive relative and absolute forms of reliability estimates for the mBPI-DPN scale, and the sSALSA scale between two testing occasions (baseline and 4-week

interval) [36]. The criteria used for the estimates of reliability were: ICC values > 0.75 excellent reliability; $0.4 > ICC < 0.75$ good reliability; and ICC values < 0.40 indicated poor reliability [37]. For interpretation of SEM% the following criterion was used: SEM% ' $\leq 20 =$ acceptable' [38]. Additionally, to assess systematic variation between tests and retest scores (baseline and 4-week interval), a paired t -test was performed. Prior to calculating the systematic bias scores, data were evaluated for assumption of normality on Kolmogorov-Smirnov (K-S) test, and Shapiro-Wilk (S-W) test [36]. If test results were nonsignificant ($p > 0.05$), it indicated the normal distribution of data, and if the results were significant ($p < 0.05$), Wilcoxon significant rank test (non-parametric test) was performed. The statistical level of significance was set at $p < 0.05$.

4.2. Analysis for convergent validity for the mBPI-DPN pain-related interference scale and sSALSA scale

Pearson's correlation coefficient [39] and/or Spearman's rank correlation [36] analyzed the association between these two variables. A coefficient of 1 indicates that the variables (mBPI-DPN pain-related interference scale and sSALSA scale) are perfectly positively correlated. The following criteria were used to assess the strength of associations: 0.00–0.25 little or no correlation; 0.25–0.50 fair relationship; 0.50–0.75 moderate to good relationship; and above 0.75 good to excellent relationship [39]. The probability (p) value was set as $p < 0.05$ (two-tailed) to examine the statistical significance of the relationship.

4.3. Analysis for responsiveness: minimal clinically important difference

Both 'anchor-based approach' and the 'distribution-based approach' were adopted to calculate and compare the interpretability scores for the mBPI-DPN and sSALSA scales. In an anchor-based approach the 'within-patient change score' method was adopted to obtain the interpretability scores. For the distribution-based methods, four different measures to calculate MCID- Standard Error of Measurement (SEM), Minimal Detectable Change (MDC), Effect size, and Standardized Response Mean (SRM) were adopted [40].

The PGIC was considered as an external criterion at 12-week follow-up [32]. For the purpose of statistical analysis, PGIC scores were clustered into two main categories: 'changed' and 'unchanged' based on previous studies [32]. Participants who scored: '5', '6', or '7' were categorized as 'changed'. The

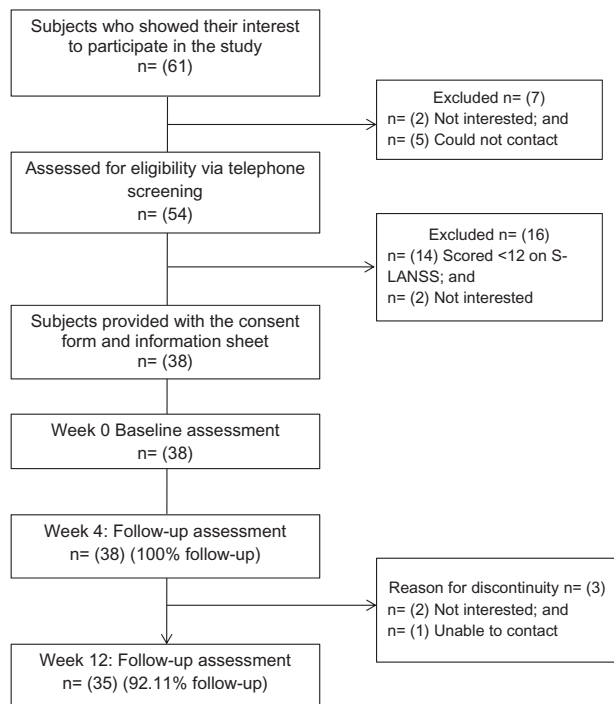


Figure 1. Flowchart of the flow of participants during study.

category unchanged' included participants who scored '1', '2', '3', or '4' on the PGIC.

To handle missing data, initially a follow-up strategy was adopted [39]. Participants who either failed to report on second assessment or failed to fill any section of the scales were contacted by telephone, or via e-mail to obtain their readings. However, if no response was obtained, then the last-observation-carried-forward method was adopted [39]. Here the participant's initial data point (before dropping out or at prior assessment) was used as the OM.

5. Results

5.1. Participant demographics

In total, 61 volunteers showed interest in participating in the study (Figure 1).

A total of 38 participants, 24 (63.2%) males and 14 (36.8%) females, with a mean age 62.7 years (SD 15.8) satisfied the inclusion criteria and gave consent to participate in the study. Table 1 presents the demographic and clinical characteristics of participants. The mean time since diagnosis with diabetes was 19.6 years (SD 14.0); mean duration of NeP was 65.8 months (SD 53.8). Less than a third were employed either part time (≤ 29 hours per week) or full-time (≥ 30 hours per week); $N=8$ (21.1%) participants reported that they were unable to work due to NeP symptoms. Less than a third of included participants ($N=12/38$, 31.6%) were retired. The mean BMI was 31.34 (range 17.68–47.25) with 21

participants classified as obese (BMI ≥ 30) [41]. The mean total pain severity and interference rating for the subjects was 47.7 (SD 20.7) (95% CI 40.9–54.5) at baseline assessment. The mean activity limitation reported by included participants was 35.6 (SD 11.1) (95% CI 31.9–39.2) at baseline assessment (Table 2).

Medicinal dosage changes occurred in 10 participants ($n=5$ at 4-week, $n=5$ at 12-week follow-up) during the study period. During the 4-week follow-up, three participants had changes in their diabetes medication dosages (two reductions, and one increase), two participants had changes in their NeP medication dosage (one reduction, and one increase). At 12-week follow-up, four participants reported an increase in their diabetes-related medication, and one reported a complete change of their medicine. None of the participants reported involvement in other forms of treatment during the study period.

5.2. Test-retest reliability

The total mBPI-DPN scale showed overall good reliability, ICC = 0.61 (95% CI 0.37–0.78); total pain severity scale, ICC = 0.57 (95% CI 0.31–0.75); and the total pain-related interference scale, ICC = 0.51 (95% CI 0.24–0.71). Results for SEM and SEM % varied widely among both of the subscales of mBPI-DPN measure. SEM (SEM %) values for the total mBPI-DPN scale ranged from 4.56 (29%) to 12.92 (28%) showing an unacceptably high level of measurement error (Criterion: SEM% ≥ 20 %). The SRD% ranged between 81 and 104 percent of the mean (Table 3). The sSALSA scale showed overall excellent reliability, ICC = 0.81 (95% CI 0.66–0.89). SEM (SEM %) values for the short form SALSA scale were 4.88 (13%) showing an acceptable (that is, <20 %) level of measurement error; SRD % value for total sSALSA scale was 13.53 (37%).

Table 3 shows the systematic variation of the mBPI-DPN and sSALSA scales mean scores, along with a *t*-test/Wilcoxon signed-rank test comparing the means at baseline and 4-week follow-up assessments. The mean change score in the mBPI-DPN pain intensity scale was 1.96 (p value 0.058), for the mBPI-DPN pain-related interference scale was 1.44 (p value 0.158), and for the total mBPI-DPN scale was 1.93 (p value 0.061). Since all the p values were >0.05 , assessment scores for the total and subcomponents of the mBPI-DPN scale are not considered significantly different at baseline and at 4-week follow-up assessments. The mean change scores for total sSALSA scale was -2.206 (p value 0.027), showing a significant difference between the baseline and at 4 weeks.

Table 1. Characteristics of participants.

Characteristic	(<i>n</i> = 38)	Range
Age (yr), mean (SD)	62.66 (15.80)	30.30–81.90
Sex, <i>n</i> male (%)	24 (63.20)	–
Ethnicity, <i>n</i> (%)	–	–
New Zealand Europeans	25 (65.80)	–
British Europeans	3 (7.90)	–
Maori	2 (5.30)	–
Indian	5 (13.20)	–
Refused to answer	2 (5.30)	–
Others	1 (2.60)	–
BMI (kg/m ²), mean (SD)	31.34 (7.60)	17.68–47.25
Waist to hip circumference ratio	0.93 (0.13)	0.81–1.30
Clinical characteristics	–	–
Type of diabetes, <i>n</i> Type I (%)	11 (28.90)	–
Type of diabetes, <i>n</i> Type II (%)	26 (68.40)	–
Type of diabetes, <i>n</i> Type Unknown (%)	1 (2.60)	–
Time since diabetes (yr), mean (SD)	19.63 (14.04)	3–53
Time with nerve pain (months), mean (SD)	65.84 (53.80)	5–204
Charlson comorbidity Index, mean (SD)	2.68 (1.80)	1–7
List of treatments availed by participants, <i>n</i> (%)	–	–
Pharmacological treatment for diabetes	23 (60.50)	–
Drugs for nerve pain	16 (42.10)	–
Drugs for other health related problems	20 (52.60)	–
Diabetic education: blood sugar monitoring, skin care, foot care	7 (18.40)	–
Physiotherapy	5 (13.20)	–
Diet management	7 (18.40)	–
Gym/Sport club participation/Exercise/Activity programme	12 (31.60)	–
Others	5 (13.20)	–

Table 2. Mean (SD) score on the mBPI-DPN and sSALSA scale by item (*n* = 38).

Item	Baseline Score	4th week score	12th week score
	Mean (SD)	Mean (SD)	Mean (SD)
mBPI-DPN item scale	–	–	–
Pain severity (0–10)	–	–	–
Worst pain over 24 h	6.26 (2.39)	5.21 (2.44)	5.03 (2.78)
Average pain over 24 h	4.76 (2.11)	3.95 (2.32)	3.66 (2.45)
Least pain over 24 h	2.79 (2.36)	2.45 (2.20)	2.13 (2.03)
Current pain	2.71 (2.37)	2.74 (2.52)	2.97 (2.64)
Total pain severity (0–40)	16.53 (6.94)	14.34 (8.13)	13.79 (8.97)
Pain-related interference (0–10)	–	–	–
General activity	4.24 (3.16)	4.08 (2.38)	4.47 (2.82)
Mood	4.13 (3.25)	3.92 (2.89)	4.26 (2.66)
Walking ability	4.66 (3.31)	4.11 (2.75)	4.29 (2.60)
Normal work	4.00 (3.08)	3.74 (2.37)	3.89 (2.57)
Relations with others	3.16 (3.20)	2.87 (2.67)	3.68 (2.99)
Sleep	5.92 (2.86)	5.00 (3.22)	4.63 (3.23)
Enjoyment of life	5.08 (2.78)	3.97 (2.43)	4.37 (2.50)
Total pain-related interference (0–70)	31.18 (15.82)	27.68 (14.70)	29.61 (15.57)
Total (0–110)	47.71 (20.72)	42.03 (21.26)	43.39 (22.70)
sSALSA scale (1–4)	Mean (SD)	Mean (SD)	Mean (SD)
See	1.42 (0.60)	1.58 (0.64)	1.50 (0.60)
Mobility (feet)	9.00 (4.30)	8.79 (3.86)	2.74 (1.13)
Self-care	4.74 (2.27)	5.11 (2.38)	1.47 (0.73)
Work (hands)	10.63 (4.82)	11.79 (5.61)	1.39 (1.22)
Dexterity (hands)	7.68 (4.05)	7.89 (3.85)	1.79 (0.91)
Total (1–80)	35.58 (11.06)	37.34 (11.52)	38.00 (11.84)

CI: Confidence Interval; hr: hour; mBPI-DPN: modified Brief Pain Inventory for Diabetic Neuropathic Pain; Ssalsa: short form Screening of Activity Limitations and Safety Awareness scale; SD: Standard Deviation.

5.3. Convergent validity

Convergent validity between mBPI-DPN pain-related interference scale (general activity, walking ability, and normal work) and sSALSA scale OMs was examined by comparing these scores using Spearman's correlation coefficient analysis (Table 4). At baseline assessment, the total mBPI-DPN pain-related interference scale showed a very low correlation with the sSALSA scale ($r = 0.45$, $p = 0.004$). Subcomponents of total mBPI-DPN pain-related interference scale: General activity ($r = 0.34$, $p = 0.039$), Walking ability ($r = 0.36$, $p = 0.026$), and Sleep ($r = 0.39$, $p = 0.017$) were fair to

moderately correlated with sSALSA scale. Only the normal work subcomponent of the mBPI pain-related interference scale showed moderate to good correlation with sSALSA scale ($r = 0.52$, $p = 0.001$). At 12-week assessment, much stronger correlations were observed between the subscales of the mBPI-DPN pain-related interference scale and the sSALSA scale: General activity ($r = 0.64$, $p < 0.001$), Walking ability ($r = 0.54$, $p < 0.001$), Normal work ($r = 0.74$, $p < 0.001$), and total BPI-DPN pain-related interference scale ($r = 0.62$, $p < 0.001$) showed moderate to good correlation. Only the sleep subscale demonstrated a low correlation with

Table 3. Descriptive and reliability statistics of the mBPI-DPN and sSALSA scales ($n = 38$).

		mBPI-DPN scale			sSALSA scale
		Pain intensity scale	Pain-related interference scale	Total mBPI-DPN scale	–
Baseline	Mean	16.53	31.18	47.71	35.58
	(SD)	(6.94)	(15.82)	(20.72)	(11.06)
	95% CI	(14.25–18.81)	(25.98–36.38)	(40.90–54.52)	(31.94–39.21)
4 weeks	Mean	14.34	27.68	42.03	37.34
	(SD)	(8.13)	(14.70)	(21.26)	(11.52)
	95% CI	(11.67–17.01)	(22.85–32.51)	(35.04–49.02)	(33.56–41.13)
<i>Relative reliability</i>		–	–	–	–
ICC _{2,1}	–	0.57	0.51	0.61	0.81
95% CI	(LB–UB)	(0.31–0.75)	(0.24–0.71)	(0.37–0.78)	(0.66–0.89)
<i>Absolute reliability</i>		–	–	–	–
SEM	–	4.56	11.05	12.92	4.88
%SEM	–	29.56	37.55	28.80	13.38
SRD	–	12.64	30.63	35.82	13.53
%SRD	–	81.93	104.09	79.82	37.09
–	–	–	–	–	–
<i>Systematic variation</i>		–	–	–	–
t/r value	–	1.96	1.44	1.93	–2.206 ^a
p value	–	0.058	0.158	0.061	0.027

CI: Confidence Interval; ICC: Intraclass Correlation Coefficient; LB: Lower boundary to confidence interval; mBPI-DPN: modified form of Brief Pain Inventory for Diabetic Peripheral Neuropathic pain; p : level of significance; r value: from Wilcoxon signed rank test; SD: Standard Deviation; SEM: Standard Error of Measurement; SRD: Standardized Response Mean; t value: from paired sample t test; UB: Upper boundary to confidence interval. ^aWilcoxon signed rank value, the sum of negative ranks equals the sum of positive ranks.

Table 4. Spearman's correlation coefficient ' r ' (p value) between mBPI-DPN pain-related interference scale and sSALSA scale.

sSALSA scale		General activity	Walking ability	Normal work	Sleep	mBPI-DPN pain-related interference scale
Baseline	r value	0.336*	0.360*	0.517**	0.385*	0.452**
	p value	0.039	0.026	0.001	0.017	0.004
12 weeks	r value	0.644**	0.541**	0.741**	0.161	0.615**
	p value	0.000	0.000	0.000	0.334	0.000

mBPI-DPN: modified Brief Pain Inventory for Diabetic Neuropathic Pain; p : level of significance; r : Spearman correlation coefficient; sSALSA: short form Screening of Activity Limitations and Safety Awareness scale.

*Correlation is significant at the 0.05 level (2-tailed).

**Correlation is significant at the 0.01 level (2-tailed).

the sSALSA scale ($r = 0.16$, $p = 0.334$). These findings suggest that the mBPI-DPN pain interference scale and the sSALSA scale measure the same constructs, and thus are convergent in nature.

5.4. Responsiveness – minimal clinically important difference

According to the external criterion used (PGIC scale), at the 12-week follow-up, $n = 5/38$ (13.16%) participants reported change in the DPN symptoms, and $n = 33/38$ (86.84%) reported no change (that is, were stable). For the two OMs (the mBPI-DPN scale and sSALSA scale), the mean and standard deviation of scores at baseline, and at 12 weeks, and the change scores, are presented as 'changed' and 'unchanged' participants in Table 5. 'Unchanged' corresponds to no/minimal change on the PGIC scale, and 'changed' to major improvement on the scale. Participants who classified themselves as 'unchanged' did not show a significant difference in their mBPI-DPN pain intensity scores, nor in their pain-related interference scores ($p > 0.05$). However, the total mBPI-DPN scale and the sSALSA scale showed significant differences

between baseline and 12-week assessment ($p < 0.05$). Participants categorized as 'changed' did not show a significant difference in the baseline and 12-week assessments for the mBPI-DPN pain intensity scale, total scale, and the SALSA scale ($p > 0.05$), except for the mBPI-DPN pain-related interference ($p < 0.05$).

Results of the MCID estimates using four different distribution-based approaches – SEM, MDC, Effect size, and SRM analysis – are given in Table 6. For the two OMs (the mBPI-DPN scale and the sSALSA scale), scores of participants who marked themselves as 'Unchanged' on the PGIC scale at 12 weeks were used for this analysis.

6. Discussion

The aim of this study was to investigate the test-retest reliability, convergent validity, and responsiveness of the mBPI-DPN and the sSALSA scale for DPN.

6.1. Test-retest reliability

The total and subscales of the mBPI-DPN score met the predefined criteria of good (>0.40 ICC <0.75)

Table 5. Mean scores and its standard deviations (at baseline, and at 12 weeks after baseline), and change scores for mBPI-DPN item and subscale and sSALSA scales arranged by PGIC categories.

Item (<i>n</i> = 33 unchanged; <i>n</i> = 5 changed)	PGIC category	Baseline score mean (SD)	Score after 12 weeks	t/r value	MCID
		95%CI (LB–UB)	mean (SD) 95%CI (LB–UB)	(<i>p</i> value)	
Total pain severity (0–40)	Un-changed	16.82 (7.11) (14.30–19.34)	14.61 (8.77) (11.50–17.72)	1.68 0.103	2.21 (–0.47–4.90)
	Changed	14.60 (5.98) (7.17–22.03)	8.40 (9.34) (3.20–20.00)	–1.483 ^a 0.138	6.20 (–3.43–15.83)
Total pain-related interference (0–70)	Un-changed	30.61 (15.95) (24.95–36.26)	30.88 (15.11) (25.52–36.24)	0.11 0.910	–0.27 (–5.17–4.62)
	Changed	35.00 (16.08) (15.04–54.96)	21.20 (17.71) (–0.79–43.19)	–2.032 ^a 0.042	13.80 (–5.74–33.34)
Total mBPI-DPN item scale (0–110)	Un-changed	47.42 (20.92) (40.01–54.84)	45.48 (21.77) (37.76–53.21)	0.70 0.492	1.94 (–3.74–7.62)
	Changed	49.60 (21.52) (22.87–76.33)	29.60 (26.44) (–3.23–62.43)	–1.753 ^b 0.080	20.00 (–7.29–47.29)
sSALSA scale (1–80)	Un-changed	36.52 (11.48) (32.45 – 40.58)	39.24 (11.99) (34.99 – 43.49)	–2.36 0.024	–2.73 (–5.08 – –0.37)
	Changed	29.40 (4.72) (23.54–35.26)	29.80 (6.98) (21.14–38.47)	–0.378 ^a 0.705	–0.40 (–3.64–2.84)

CI: Confidence Interval; LB: Lower Boundary to confidence interval; mBPI-DPN: modified Brief Pain Inventory for Diabetic Peripheral Neuropathy; PGIC: Patient Global Impression of Change scale; *p*: level of significance; *r* value: from Wilcoxon signed rank test; sSALSA: The short form Screening of Activity Limitations and Safety Awareness scale; SD: Standard Deviation; *t* value: from paired *t* test; UB: Upper Boundary to confidence interval.

MCID and 95 % CI values set in italics indicate statistically significant differences between mean changes.

^aThe sum of negative ranks equals the sum of positive ranks from Wilcoxon signed rank test.

^bBased on positive ranks from Wilcoxon signed rank test.

Table 6. MCID values (at 95% confidence intervals) for the subscales of mBPI-DPN scale and sSALSA scale when using four different distribution-based methods.

Item	Absolute change score using six different MCID methods of distribution-based approach			
	SEM	MDC	Effect size	SRM
Baseline to 12 weeks follow-up (<i>n</i> = 33)		–	–	–
Total pain severity	4.84	13.41	–0.31	–0.25
Total pain-related interference	9.94	27.54	0.02	0.02
Total mBPI-DPN item scale	11.03	30.58	–0.09	–0.09
sSALSA scale	4.84	13.42	0.24	0.23

mBPI-DPN: modified Brief Pain Inventory for Diabetic Peripheral Neuropathy scale; MCID: Minimal Clinically Important Difference; MDC: Minimal Detectable Change; sSALSA: the short form Screening of Activity Limitations and Safety Awareness scale; SEM: Standard Error of Measurement; SRM: Systematic Response Mean.

reliability. Current findings have both similarities and differences to previous test–retest evaluations [22–25]. Although there may be variability between studies, previous results demonstrated that the test–retest reliability of the mBPI-DPN scale is highest when administered over a short time span (that is, hourly or daily), as compared with the four weeks duration in the current study, suggesting that these may be the optimal intervals for assessment with this tool during future. This was the first study to report on the relative as well as the absolute forms of reliability for mBPI-DPN scale in the DPN population. In the current study, the total short form SALSAscale demonstrated excellent reliability (ICC = 0.81). There are no comparative data within the literature, as this was the first attempt to evaluate the test–retest reliability of sSALSAscale in DPN population.

While both the subcomponents and total mBPI-DPN scale and sSALSAscale demonstrated good to excellent relative reliability, the absolute reliability results (SEM % and SRD %) were not within the acceptable range (criterion, SRD % ≤20%). The SEM value is crucial in the correct interpretation of ICC results, as it indicates the amount of ‘measurement

noise’. The SEM values for this study suggests that test–retest differences of <28% for the mBPI-DPN scale and <13% for the sSALSAscale should be considered as measurement noise in DPN participants. Similarly SRD of a test/measure can be useful for clinicians or researchers in determining whether the change in score for an individual is real (that is, beyond measurement error) at 95% confidence interval [38]. On the basis of the SRD% observed in the current study, a general guideline for DPN patients is that a 79% change in the pain scores and 37% change in the physical function scores are indicative of a genuine clinical change. This higher variability in the absolute reliability values represent the subtle differences between two assessments; thus, the obtained results should be interpreted with caution.

Collectively it is understood that the test–retest reliability of the mBPI-DPN scale is good; furthermore the sSALSAscale demonstrated excellent reliability.

6.2. Convergent validity

The aim of the second part of the current study was to evaluate the validity of the sSALSAscale using

mBPI-DPN pain-related interference scale as the gold standard. The correlation between sSALSA scale and the mBPI-DPN pain interference scale was fair to moderate at baseline assessment. However, a much stronger correlation ($r = 0.54\text{--}0.74$, $p < 0.001$) was observed at the 12-week follow-up point. This increase could be due to the increased variability in the pain scores, and thus the pain-related interference scores at 12 weeks. Based on these results, it is concluded that sSALSA scale can be used as a substitute to BPI pain interference scale to measure physical function in patients with DPN.

Previous studies have highlighted the potential of the sSALSA scale. When evaluated for its convergent validity in a leprosy-based NeP population ($n = 38$ participants) against the DASH questionnaire, the measure showed a very good correlation (Spearman's correlation $r = 0.87$, $p < 0.001$), demonstrating its ability to be used as a measure of physical activity in this population [42]. In another leprosy-based study ($n = 25$ participants), the sSALSA scale showed a moderate to good correlation with various measures of hand functions: Nine Hole Peg test ($r = 0.77$, $p < 0.0005$); the Smith Hand Function Evaluation ($r = 0.66$, $p < 0.0005$); the Functional Dexterity Test ($r = 0.63$, $p < 0.0005$); and the timed scored Functional Dexterity Test ($r = 0.54$, $p < 0.005$) [43]. Current findings in the DPN population further validate the usage of sSALSA scale in the DPN population as a measure of physical function.

6.3. Responsiveness

The next part of this study identified the range of MCID values for the pain (mBPI-DPN item scale) and physical function (sSALSA scale) OMs for the DPN population. For the anchor-based approach, only 'within-patients change score' method was adopted. In addition, this study compared the four common methods within the distribution-based approach to help gain a better understanding of how methodological variations can alter the interpretability of the MCID; the different approaches used provided a very different results (SEM, MDC, Effect Size, and SRM).

SEM: In the current study, SEM was used as one distribution based method to find the MCID for the total and subcomponents of the mBPI-DPN and sSALSA scales. Through this calculation, it is possible to describe the amount of change that would need to be observed on the scale to exceed measurement error. The SEM calculated in this study provides a minimum change score, which indicates a real change in a patient, rather than the measurement error alone [44].

MDC: As only unchanged participants were assessed to calculate the MCID, it was assumed that

for calculating the minimal important difference in the mBPI-DPN scale, and in the sSALSA scale, the MCID value should exceed the MDC values. Thus participants with a change score \leq MDC have a chance that no real change has happened in their clinical condition. The MDC is considered as a conservative method for calculating MCID, as the measurement error is multiplied by $\sqrt{2}$ at 95% confidence intervals, accounting for the so-called 'background noise'. In the current study, MDC = 13.4 points was calculated for mBPI-DPN pain intensity scale (0–40 points scale), which means a change of more than 13.4 points could be considered as a MCID for this subscale. Similarly for the mBPI-DPN pain interference scale (0–70 points scale), MDC = 27.5; for the total BPI-DPN scale (0–110 points scale), MDC = 30.6, and for total sSALSA scale (1–80 points scale), MDC = 13.4 was calculated.

Effect size: For the mBPI-DPN pain intensity scale, the mBPI-DPN pain-related interference scale, total mBPI-DPN scale, and sSALSA scale at all the respective assessments, an effect size of $\leq 0.20 < 0.50$ was observed, showing that there was a very small effect change in pain and physical function scores over time, as expected. Because of the smaller effect size values, it could be stated that for the 12-week study duration, no significant change of pain or physical function status occurred in the studied population.

SRM: In the current study, the mBPI-DPN pain intensity scale, the mBPI-DPN pain-related interference scale, the total mBPI-DPN scale, and the sSALSA scale were believed *a priori* to be likely not to change, as no intervention was involved. Using SRM for all these outcomes, a very small change < 0.20 was observed, showing that there was a very small effect change in the pain and physical function scores over time.

The above methods produced a variability in the MCID scores for the two used OMs (mBPI-DPN scale and sSALSA scale). The possible explanation for this variation in the MCID, according to the methods of estimation, can be due to the multiple reported conceptual and methodological differences [45]. Furthermore, baseline scores of the measures, as well as the demographics of the studied population, may have an effect in MCID values as the more extreme baseline scores will have lower SEM and therefore smaller MDCs. [40,46]. In reviewing MCID estimates for other pain scales and in other pain populations, findings appear to be consistent with findings related to mBPI-DPN presented in this study. For comparing findings of this responsiveness study, no comparative data were available as this is the first study to calculate MCID of the pain (mBPI-DPN scale) and physical function (sSALSA scale) OM in DPN. The only comparative

data available are from fibromyalgia and cancer-related populations.

In this study, a range of MCID for pain and physical function OMs have been presented. In research a MCID value has to be chosen *a priori* to judge which changes are worthwhile to detect. In practice, an MCID value can be used to interpret results of a treatment [47]. Capturing responsiveness to change is a very important property of an OM. A particular measure could be oversensitive and pick up small or unimportant changes in health. Alternatively, a particular questionnaire could be under sensitive and miss important changes because they are small [44]. Thus ongoing research to understand how best to measure change for these methodological studies is required. The analysis used in this study has supported the view that the choice of statistic will affect the description of responsiveness for any OM. For the same data in the same patients, we have demonstrated a variation in the responsiveness values using different statistics. These findings are in concordance with the available literature [44]. These results do not confirm which approach is better, as arguments can be made in either direction. Though there is a significant difference in the findings of these two methods, approaches directed toward combining the distribution- and anchor- based methods should be the focus of clinical reports [48,49].

6.4. Limitations of the present study

While results for this reliability study are good, there are several limitations which need to be acknowledged. The target sample of 63 participants for the reliability study was not met (as calculated by Walter's equation [27,50], which potentially threatens the statistical significance of the present results. For the present study, the included participants demonstrated a good degree of heterogeneity in terms of age, severity of symptoms, and duration of symptoms, and the included sample size is similar to previous studies in the field [24,51]. However, it is acknowledged that while performing the data analysis, how alteration of medication may have impacted on responsiveness or reliability was not considered.

For the responsiveness study, from $n = 38$ recruited participants, just 5 participants identified themselves 'as being changed from baseline assessment' which may have affected the precision estimates. As intensity of pain is an important factor, the MCID was planned to be estimated for mild, moderate, and severe levels separately. However, as only a very small number of participants were recruited for this study, it was not possible to perform the sub analysis on such small numbers.

Similarly for the various available anchor-based approaches, only 'within-patient change score' was used in this study. For the other available methods, 'between patient change score', 'ROC curve', and the 'social comparison approach', statistical analysis was not possible because of the smaller sample size.

6.5. Future research recommendations

In this study, a number of the psychometric properties of pain and physical function OMs were assessed in a DPN population. Of the six core outcome domains recommended by the IMMPACT [10], the EFNS [11] and NeuPSIG [12] guidelines, psychometric properties for only first two domains, that is, pain and physical functioning, were addressed and investigated. Further research studying various OMs in the other four domains, i.e. 'Emotional functioning', 'Participants' rating of overall improvement', 'Participants' satisfaction with treatment and symptoms', and 'adverse events', and the psychometric properties of those OMs, is indicated.

Validation is an ongoing process. In order to generalize results of the present study, a similar procedure should be repeated on a larger (≥ 100) number of participants. Such a study is required to enable more detailed statistical analysis of OMs to investigate their psychometric properties. Such a large number of participants would necessitate an extended recruitment period. Future investigators exploring the psychometric properties of various OMs should consider various time points (from days to weeks, to months to years) to capture the natural progression of the underlying disease. The inclusion of scales quantifying mood, sleep pattern, and health-related quality of life may provide a better understanding of influence of pain on these domains.

Since there has been much debate over whether to use the anchor- or distribution-based approach in determining the MCID of an OM, future research attempting to establish MCID values for any self-reported measure should use objective (clinician reported) anchors, or a combination of subjective (patient reported) and objective anchors, rather than linking two self-reported instruments to each other in the belief that one of the two (such as global rating of change, GRC, or patient global impression of change, PGIC) can be used as an 'objective' anchor of outcome. In the literature, most of the studies have been performed to evaluate MCID for significant change or improvement. Future research should evaluate if the MCID value for improvement is the same as for deterioration.

6.6. Clinical implications

Results from this study add to the body of evidence surrounding the usability of various OMs used to evaluate the effectiveness of various treatments of NeP and DPN, which the clinician/researcher can use as part of the informed decision-making process that underpins evidence-based practice. This observational study was designed and undertaken to investigate the psychometric properties of OMs for the assessment of DPN. With the usage of these reliable and valid multidimensional PROMs, patients/research participants may themselves track the progression (improvement/deterioration) of their condition/clinical symptoms.

7. Conclusions

This study was developed to explore and investigate the psychometric properties of various pain and physical function OMs in DPN population. Despite the limitations and problems encountered during completion of the study, results have provided evidence to add to the scientific basis surrounding the use of pain and physical functioning OMs in the DPN population. To assess pain and pain-related physical functional limitation is very important in any condition associated with sensory loss. This study has provided preliminary values for test–retest reliability, convergent validity, and responsiveness (capturing the natural progression/variation of the disease) of mBPI-DPN and sSALSA scales in the DPN population. However, issues around assessing the responsiveness under the influence of clinical treatment remain. Since the different modes of administration of questionnaires can have an important influence on the quality of the information collected, it is acknowledged that the findings of the sSALSA scale in this study may not be generalizable to a wider population, before further validation. However, standardization of these measures in a larger population may provide the gold standard to use in research and clinical practice.

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previously submitted or are under consideration at any other journal.

Disclosure statement

All authors declare that there exist no conflicts of interest associated with the current study, and corresponding author's email address can be published.

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Dr. Poonam Mehta's doctoral research was in the area of Neuropathic pain and was completed in 2015; her thesis was entitled "Neuropathic pain: Outcome measures and their psychometric properties". This study focused on identifying the reliable and valid outcome measures for diabetic neuropathic pain. Her current research interests are in the health and wellbeing of ageing people and through her current roles she is further developing her skills and passion for research in the area of ageing health and wellbeing. Professor David Baxter TD is currently Director for the New Zealand National Science Challenge for Ageing Well. David's research expertise is in the fields of rehabilitation, low back pain, complementary and alternative medicine, as well as in laser medicine. His current projects include physical activity interventions (principally walking interventions) for health, photobiomodulation of delayed wound healing, and clinical effectiveness of acupuncture (including laser devices) as an alternative to needles in treatment of pai.

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