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Original Article

Physiotherapy Section

Reliability of Digital Pressure Algometer in Painful Diabetic Peripheral Neuropathy: A Quantitative Cross-sectional Study

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ABSTRACT

Introduction: Painful Diabetic Peripheral Neuropathy (PDPN) is associated with pain and disturbed sensory symptoms. Altered Pressure Pain Threshold (PPT) in PDPN often leads to complications of diabetic foot and consequent amputations. Early detection of altered PPT can prevent future complications and reduce mortality rates. PPT may be determined with a pressure algometer, which measures the pressure and/or force at which the first perception of pain begins. The cost of algometers frequently prevents them from being used in clinical and research settings. An affordable and dependable algometer would be a valuable tool in PDPN, where health costs are already 20% higher than those of diabetic controls.

Aim: To evaluate the test-retest and inter-rater reliability of a low-cost digital pressure algometer in individuals suffering from PDPN.

Materials and Methods: This quantitative cross-sectional study was conducted for four months at Metro Heart Institute with Multispeciality Hospital, Faridabad, Haryana, India. PPT of 30 patients with PDPN aged 50-70 years (mean age 61.53±5.84 years) was collected twice by one rater (R1) after a gap of 24 hours. Another rater (R2) repeated the first reading at similar points on both feet. PPT was noted at the dorsum, 2nd, and 3rd metatarsal on the plantar surface of the foot. The main outcome measurements were the Intraclass Correlation Coefficient (ICC), Standard Error of Measurement (SEM), Minimal Detectable Change (MDC), and using the Bland-Altman approach, measurement bias was evaluated.

Results: The ICC for test-retest reliability for the dorsal right and left foot was 0.85 and 0.83, respectively. The ICC for Plantar 2nd metatarsal right and left was 0.86 and 0.89, respectively. The ICC for the plantar third metatarsal right and left foot was 0.85 and 0.81, respectively. The inter-rater reliability ICC values varied from 0.63 to 0.87. Bland-Altman plots showed acceptable levels of agreement.

Conclusion: The digital algometer showed good test-retest and moderate inter-rater reliability in patients with PDPN.

Keywords: Inter-rater reliability, Pressure pain threshold, Test-rest reliability

INTRODUCTION

Pain measurement is important in clinical practice and as an outcome measure in research. PDPN is characterised by crippling pain that can be burning, electric, lancinating, or shooting [1-3]. It presents as a glove and stocking distribution of pain and sensory symptoms and is characterised by the degeneration of nociceptors, or free nerve endings of unmyelinated C-fibers and thinly myelinated A-delta fibers, followed by the demyelination of large, myelinated A-ß fibers with disease progression [4]. Tissue injury from any mechanical impact causes hypersensitivity in the affected area, and pain perception thresholds are lowered accordingly so that light touch and palpation may elicit pain that can prevent further damage in normal subjects [5,6]. On the contrary, in PDPN, there is numbness, paraesthesia, or pain sensitisation following normally non painful stimulation and abnormally increased sensitivity to pain due to the degeneration of nociceptors [7]. To create a prospective evaluation, compare baseline results to other temporal evaluations, or even use the data as a prognostic indicator to forecast future outcomes, an objective pain assessment is necessary [8]. There are 13 distinct mechanical and thermal tests in standardised quantitative sensory testing [9]. One is digital pressure palpation, commonly used in clinical practice to detect and assess pain. However, because patients report pain in a subjective manner and different examiners apply different pressures, it can be difficult to measure and standardise this approach [10]. PPT has a predictive ability as a useful prognostic indicator in patients with PDPN. Since conventional pressure algometry can activate nociceptors, high-threshold mechanoreceptors at the ends of A-delta and C-fibers, and low-threshold mechanoreceptors at the ends of A-beta fibers [11-13], it can prove to be a valuable tool in the assessment of PDPN.

Intraepidermal electrical stimulation has been used by far to assess small fiber pain threshold values in diabetic neuropathy [14]. Deep PPT has also been measured in painless diabetic neuropathy using a pressure algometer [15,16]. Another study has used a pressure algometer to assess deep PPT in patients with unilateral foot trauma, severe painless diabetic neuropathy, and chronic foot pathology [16]. PPT in painless diabetic neuropathy, plantar injury, non neuropathic, as well as acute painful skeletal injury patients, has also been assessed using a pressure algometer [5].

Despite being an important diagnostic tool, a pressure algometer is limited in clinical and research practices due to associated costs. An adapted low-cost digital algometer can prove to be an asset. The instrument used in the present study was similar to the one used by Jerez-Mayorga D et al., [17], but the manufacturing company (Biotronix Care) was different in the present study. The Biotronix Care company has not conducted or published any reliability study until now. Previously, a validity and reliability study of a pressure algometer (MiotecTM Biomedical Equipment, Porto Alegre, RS, Brazil) was found in the literature on healthy subjects, where pressure thresholds were measured at the middle deltoid area [17]. The novelty of present study was to establish the test-retest and inter-rater reliability of the digital pain pressure algometer (Biotronix Care, Mars One, India) in the population of PDPN, a neurological condition. The concerned population has high clinical significance because if the condition is not appropriately diagnosed at the right time and the correct progressive stage of the disease, it may result in plantar foot ulcers, diabetic foot ulcers, and, thus, amputations. There is a need to explore the reliability of the digital pressure algometer in PDPN in different populations and pain conditions that can prove clinical relevance. This study aimed to evaluate the reliability of the digital pressure algometer in PDPN.

MATERIALS AND METHODS

This quantitative cross-sectional study was conducted in the Department of Endocrinology, Metro Heart Institute with Multispeciality, Faridabad, Haryana, India. The study was conducted for four months i.e., September 2023 to December 2023.. The hospital ethics committee ethically approved the study with EC registration number ECR/945/Inst./HR/2017, dated 6.9.23.

Inclusion criteria: Thirty consecutive patients diagnosed with Diabetes Mellitus (DM) with ≥7 years and with lower extremity symptoms for ≥6 months in the age group of 50-70 years, 17 males, and 13 females, were screened by an endocrinologist and included in the study. Patients who can stand on both feet using walking aids or independently and have a Body Mass Index (BMI) between 18 and 29.9 kg/m^2 [18,19], Neuropathy Disability score (NDS) more than 3 [20], and Leeds Assessment of Neuropathic Symptoms and Signs score (LANSS) ≥12 [21,22] were included.

Exclusion criteria: Patients with a history or evidence of neurological disorders other than neuropathy associated with DM, musculoskeletal dysfunctions like scoliosis, lumbar disc prolapse, and lumbar spine-associated radiculopathy, previous low back surgeries and lower limb surgeries, plantar foot ulcers, severe nephropathy, severe retinopathy, severe hepatic disorders, and significant cardiovascular impairment were excluded from the study.

Study Procedure

After obtaining proper consent from the included patients, independently trained raters (R1 and R2) took readings of PPT using a digital pressure algometer (Biotronix Care, Mars One SKU: SF1005, India) with a probe of 1 cm^2 at three areas: one on the dorsum of the foot, a little below the first web space; one on the plantar foot surface over the second metatarsal; and another one on the plantar surface of the third metatarsal on both feet one by one [Table/Fig-1], with a gap of 30 minutes. The first rater (R1) only took the second reading on the same areas after 24 hours. The PPT points were marked and palpated by the same rater. Both raters were trained in the consistent application of pressure on the algometer. The patient indicated when the applied pressure provoked pain or when the PPT was reached. After locking the reading by pressing the "tare" button, the examiner quickly withdrew the modified pressure algometer and recorded the PPT.

[Table/Fig-1]: Measurement of Pressure Pain Threshold (PPT) using pressure algometer at: (a) dorsum; (b) 2nd metatarsal of plantar surface; and (c) 3rd metatarsal of plantar surface.

Calculation of SEM and MDC:

SEM was measured using the formula [8,23]: SEM=SD √1-ICC

Where: SEM: Standard error of measurement; SD: Standard deviation of the first and second readings of the first rater in test-retest reliability and the mean SD of the first reading of the first and second rater. The 95% CI of ICC values was also calculated.

MDC was calculated with the formula [24]: MDC=SEM×1.96 √2. Where, MDC gives the minimum value for a difference to be considered "real".

STATISTICAL ANALYSIS

All statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) version 20.0, with the level of significance set at 0.05. The demographic data were analysed using descriptive statistics. The normality of the data was assessed using the Shapiro-Wilk test, histogram, and skewness plot. The paired t-test was used to evaluate systematic errors between raters and measures. To examine the reliability of PPT in PDPN, the test-retest and inter-rater reliability were computed using a two-way mixed model. The ICC (3,1) with absolute agreement was calculated. ICC values <0.5 denoted poor reliability, 0.5 to 0.75 suggested moderate reliability, 0.75 to 0.9 denoted good reliability, and >0.90 denoted excellent reliability [25]. Bland-Altman plots were used to quantify measurement bias. They graphically represent differences between two consecutive PPT measurements by the same rater and between two different raters [26].

RESULTS

The demographic characteristics are presented in [Table/Fig-2]. No outcome measures showed any non normal distribution.

Characteristics	Mean±SD
Age (years)	61.53±5.84
Height (m)	1.63±0.09
Body weight (kg)	71.66±8.92
Body Mass Index (BMI) (kg/m^2)	26.81±2.87

[Table/Fig-2]: Demographic characteristics of the participants.

Every research participant tolerated pressure algometry with ease. The ICC for test-retest reliability was good for all three anatomical locations of both feet. The ICC at the dorsum was 0.85 and 0.83 for the right and left foot, respectively. The ICC for the plantar 2nd metatarsal was 0.86 and 0.89 for the right and left foot, respectively. The ICC for the plantar 3rd metatarsal was 0.85 and 0.81 for the right and left foot, respectively. The SEM values varied between 0.49 and 0.92, and MDC varied from 1.37 to 2.56 [Table/Fig-3]. A paired t-test indicated no significant difference between test-retest values of PPT at the dorsum, plantar 2nd, and 3rd metatarsal sites in the left and right foot.

Variable	First reading of R1 Mean±SD	Second reading of R1 Mean±SD	p-value	ICC	95 %CI	SEM	MDC
Dorsum right (kg)	4.03±1.32	3.90±1.20	0.38	0.85	0.69-0.93	0.49	1.37
Dorsum left (kg)	4.13±1.62	3.91±1.34	0.24	0.83	0.64-0.91	0.60	1.68
Plantar 2nd MT right (kg)	5.49±2.18	5.00±1.79	0.06	0.86	0.71-0.93	0.73	2.03
Plantar 2nd MT left (kg)	5.44±1.85	5.43±1.96	0.94	0.89	0.76-0.94	0.62	1.74
Plantar 3rd MT right (kg)	5.88±2.06	5.65±1.95	0.38	0.85	0.69-0.92	0.76	2.11
Plantar 3rd MT left (kg)	6.28±2.08	5.73±2.26	0.06	0.81	0.62-0.91	0.92	2.56

[Table/Fig-3]: Results of test-retest reliability of Pressure Pain Threshold (PPT) using pressure algometer at dorsum and plantar surface 2nd and 3rd metatarsal for right and left foot.
MT: Metatarsal; ICC: Intra-class correlation coefficient; CI: Confidence interval; SEM: Standard error of measurement; MDC: Minimal detectable change

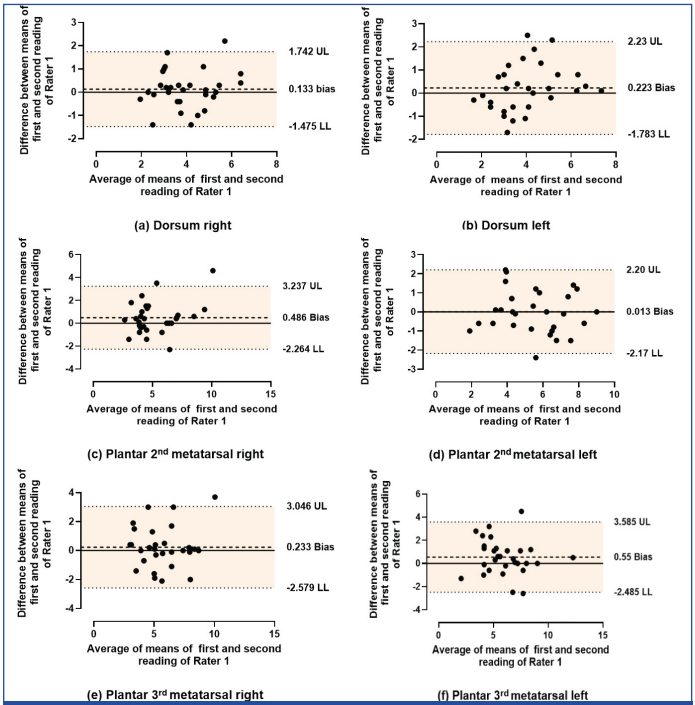
ICC for inter-rater reliability was good, with values of 0.75 for the dorsum of the right foot and 0.76 for the dorsum of the left foot. ICC values for the plantar 2nd metatarsal showed moderate reliability, with values of 0.69 and 0.67 for the right and left foot, respectively. Additionally, ICC values for the plantar 3rd metatarsal were found to be moderately reliable for the right foot, with a value of 0.63, and good reliability for the left foot, with a value of 0.87. SEM varied

between 0.63 and 1.22, and MDC was 1.51 and 3.38 [Table/Fig-4]. The paired t-test indicated no significant difference between rater 1 and rater 2 values of PPT at the dorsum, plantar 2nd, and 3rd metatarsal sites in the left and right foot, except for the left foot dorsum surface (p-value <0.001). Although the standard deviation for the same is small, such results can possibly be due to variation in pressure application between the two raters.

Variable	First reading of R1 Mean±SD	First reading of R2 Mean±SD	p-value	ICC	95 %CI	SEM	MDC
Dorsum right (kg)	4.03±1.32	3.69±1.22	0.10	0.75	0.48-0.88	0.63	1.51
Dorsum left (kg)	4.13±1.62	3.41±1.05	<0.001*	0.76	0.42-0.89	0.65	1.80
Plantar 2nd MT right (kg)	5.49±2.18	5.15±1.74	0.33	0.69	0.35-0.85	1.09	3.02
Plantar 2nd MT left (kg)	5.44±1.85	5.22±2.07	0.53	0.67	0.32-0.84	1.11	3.07
Plantar 3rd MT right (kg)	5.88±2.06	5.71±2.00	0.66	0.63	0.22-0.82	1.22	3.38
Plantar 3rd MT left (kg)	6.28±2.08	5.76±2.35	0.06	0.87	0.72-0.93	0.79	2.19

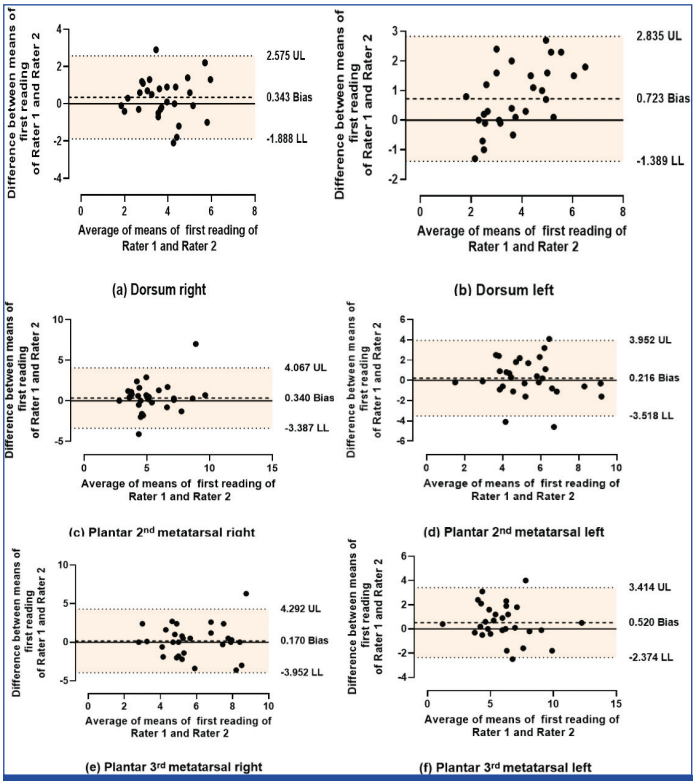
[Table/Fig-4]: Results of interrater reliability of pain pressure threshold using pressure algometer at dorsum and plantar surface 2nd and 3rd metatarsal for right and left foot. MT: Metatarsal; ICC: Intra-class correlation coefficient; CI: Confidence interval; SEM: Standard error of measurement; MDC: Minimal detectable change; *: significant difference

Bland-Altman plots for test-retest reliability showed acceptable levels of agreement [27]. The indicated line of bias was close to zero for the dorsum, plantar 2nd, and 3rd metatarsal of both the right and left foot. The bias between the first and second reading was found to be 0.133 for the dorsum right, 0.223 for the dorsum left, 0.486 for the plantar 2nd metatarsal right, 0.013 for the plantar 2nd metatarsal left, 0.233 for the plantar 3rd metatarsal right, and 0.55 for the plantar 3rd metatarsal left. However, only one or two data points showed values outside the outliers [Table/Fig-5].



[Table/Fig-5]: Bland-Altman plots representing graph of mean difference and average of first reading and second reading of rater 1 at: (a) dorsum right; (b) dorsum left; (c) plantar 2nd metatarsal right; (d) Plantar 2nd metatarsal left; (e) Plantar 3rd metatarsal right; (f) plantar 3rd metatarsal left.
Each dot represents difference between two measurements plotted against mean of two measurements of same rater (Rater 1). Horizontal line represents mean value of the difference for 30 patients, dotted lines represent upper and lower limits of agreement

Similarly, Bland-Altman plots for inter-rater reliability also showed acceptable levels of agreement for all three anatomical sites of both feet as a line of bias is close to zero, except for the dorsum left, which was 0.723. The bias between readings of both raters was found to be 0.343 for the dorsum right, 0.340 for the plantar 2nd metatarsal right, 0.216 for the plantar 2nd metatarsal left, 0.170 for the plantar 3rd metatarsal right, and 0.520 for the plantar 3rd metatarsal left [Table/Fig-6].



[Table/Fig-6]: Bland-Altman plots representing a graph of mean difference and average of first readings of rater 1 and rater 2 at: (a) dorsum right; (b) dorsum left; (c) plantar 2nd metatarsal right; (d) Plantar 2nd metatarsal left; (e) Plantar 3rd metatarsal right; (f) plantar 3rd metatarsal left.
Each dot represents the difference between two measurements plotted against the mean of measurements of two raters (Rater 1 and Rater 2). The horizontal line represents the mean value of the difference for 30 patients; dotted lines represent the upper and lower limits of agreement

Each dot represents the difference between two measurements plotted against the mean of measurements of two raters (Rater 1 and Rater 2). The horizontal line represents the mean value of the difference for 30 patients; dotted lines represent the upper and lower limits of agreement.

DISCUSSION

This study assessed the test-retest and inter-rater reliability of a digital low-cost pressure algometer in patients with PDPN. The results of this study showed good test-retest reliability and moderate inter-rater reliability according to the criteria provided by Koo TK and Li MY [25]. The study population chosen for the reliability analysis of PPT in PDPN had a mean BMI of 26.81±2.87 (kg/m^2), which is considered normal to avoid any bias in results due to changes in plantar pressure distribution of weight and decreased pain sensitivity, factors commonly observed in obese individuals and considered important while assessing PPT in previous studies [19,28].

The ICC values were between 0.81 and 0.89 for test-retest, with low SEM and MDC suggesting that the measurement error is small in relation to between-session variability [29]. The results of present study were comparable to other investigations showing good to excellent intra-rater reliability of 0.81-0.99 for measuring PPT in healthy young adults [30], in patients

with knee pain [31], and with another study that reported test-retest ICC of 0.72-0.95, where the first rater repeated the PPT measurement after 24 to 72 hours using a digital algometer for the piriformis muscle [32]. Walton D et al., reported ICC of 0.76-0.79 for test-retest reliability of a digital algometer in patients with and without neck pain, where a second reading by the same rater was taken after three to five days [8]. This suggests that the time gap between two measurements of the same rater may play a role in test-retest reliability and should be observed carefully.

The inter-rater reliability was at moderate to good levels, with ICC values between 0.63 and 0.87 and SEM values between 0.63 and 1.22 for PPT using a pressure algometer. These results are comparable to a study that measured the reliability of the algometer in children with orthopaedic disorders [33]. Both studies share the similarity of a 30-minute time gap between the assessment of different raters and the training status of the raters. However, in another study by de Oliveira AK et al., they reported ICC values of 0.85 and 0.87 when readings of PPT were taken one week apart in women with myofascial trigger points of the right and left trapezius [34]. Additionally, in the present study, a significant difference between the two raters was found only for the left dorsum surface. Some authors suggest that the possible reason for this difference could be differences in gender [35], age, or professional status [36], and the placement technique of the two raters. In this study, both raters were female and measured PPT in the previously marked areas, but their professional status and age varied, which may have contributed to the lower ICC values in inter-rater reliability compared to test-retest reliability. Furthermore, the difference in the application of force between the two raters could also contribute to such differences in results. This suggests that proper training is essential for the application of constant pressure while using the algometer for measuring PPT in the patient population. Such changes in readings between two raters can also be attributed to patient response due to a change in pressure threshold between the two assessments in a painful condition like PDPN.

Similarly, another study showed that inter and intra-rater reliability has been documented for the middle deltoid muscle's PPT in a healthy population. The ICC for intra-rater reliability was 0.76 for rater 1 and 0.73 for rater 2, and inter-rater reliability ranged from 0.56 on day 1 to 0.54 on day 2 [17]. According to raters or measurement frequency, PPTs have a rather good dependability [37]. On the contrary, some authors also reported that pressure algometers showed high reliability between observers for measurements of normal muscles [38], while others investigated the reliability of pressure algometers in myofascial trigger points and showed high reliability between different raters [34,39].

Previous research has demonstrated that a variety of digital algometry systems exhibit reasonable levels of reliability [40]. Various researchers have also evaluated the precision of various pressure algometers to distinguish between those who are healthy and those who have musculoskeletal issues [8,24]. Other studies by some authors examined the reliability of pressure algometers in healthy individuals for the knee using a hand-held electronic pressure algometer [41], the foot and face using a hand-held dynamometer [42], the head and neck using a force gauge [38], low back pain using an electric pressure algometer [43], the wrist, leg, cervical, and lumbar spine using a digital pressure algometer [30]. Other types of algometers used so far were computerised pressure algometer to evaluate PPT in back pain [44] and modified syringe algometer in coccydynia [45].

In the past, a variety of studies have shown the usefulness of pressure algometers in measuring PPT and sensory complaints in musculoskeletal diseases such as low back, shoulder, and neck pain [46-51], knee pain in arthritis [52], fibromyalgia [53], temporomandibular disorders [54], and other myofascial trigger points [55]. A digital algometer has also been used in the assessment of PPT in severe painless diabetic neuropathy after skeletal foot trauma [16], in acute painful skeletal injury and diabetic foot in the ulcerative stage [5], in patients without neuropathy as well as in diabetic foot syndrome [15]. Digital algometry methods have demonstrated respectable levels of validity and reproducibility in diabetic patients, according to prior research. However, limited research is available regarding the use of pressure algometers in neurological conditions like PDPN.

Some authors also suggest that algometry is not suitable to measure PPT in painless diabetic peripheral neuropathy due to the loss of deep tissue nociceptors [15]. However, in PDPN patients, hyperalgesia, allodynia, or hypoesthesia can be observed depending on the severity and duration of neuropathy [1,56,57]. Therefore, it could prove to be an effective non invasive technique for assisting with early diagnosis and potential prevention of PDPN. According to the findings, the tested gadget is sufficiently reliable to be considered standard equipment for assessing individuals with PDPN's PPT. The reviewed item seems to be a good alternative to expensive gadgets. PDPN describes a population with impaired sensations, which may present with negative symptoms like numbness or positive symptoms like allodynia or hyperalgesia. Therefore, assessing the degree of damage to plantar pain receptors is of utmost importance at the correct time before it results in non healing foot ulcers and consequent foot amputations. Thus, measuring the PPT in PDPN patients can help prevent the deterioration of symptoms. Since the use of a pressure algometer is limited due to the associated expenses, the availability of such a low-cost, reliable algometer can prove to be of high clinical significance. Further studies proving the reliability of the instrument on different populations and broader demographics could be helpful in future research.

Limitation(s)

The present study included patients aged 50-70 years, who may also exhibit age-related decline in sensory functions. Although PDPN presents as small fiber neuropathy, there is consequent involvement of large diameter fibers with disease progression, and the patients in this study were not selected based on the severity of symptoms, which could lead to differences in PPT. It is recommended to include patients across a wider age range and consider the severity of symptoms to obtain more precise results and generalise them to a broader population of PDPN.

CONCLUSION(S)

This study demonstrated good test-retest and moderate inter-rater reliability of digital algometers used to quantify PPT in patients with PDPN, suggesting that they could serve as a useful alternative to expensive algometers currently available.

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