

Original Article

Reliability and responsiveness of algometry for measuring pressure pain threshold in patients with knee osteoarthritis

EBRU KAYA MUTLU, PT, PhD^{1)*}, ARZU RAZAK OZDINCER, PT, PhD¹⁾

¹⁾ Division of Physiotherapy and Rehabilitation, Faculty of Health Sciences, Istanbul University: 34093 Bakirkoy, Istanbul, Turkey

Abstract. [Purpose] This study aimed to establish the intrarater reliability and responsiveness of a clinically available algometer in patients with knee osteoarthritis as well as to determine the minimum-detectable-change and standard error of measurement of testing to facilitate clinical interpretation of temporal changes. [Subjects] Seventy-three patients with knee osteoarthritis were included. [Methods] Pressure pain threshold measured by algometry was evaluated 3 times at 2-min intervals over 2 clinically relevant sites—mediolateral to the medial femoral tubercle (distal) and lateral to the medial malleolus (local)—on the same day. Intrarater reliability was estimated by intraclass correlation coefficients. The minimum-detectable-change and standard error of measurement were calculated. As a measure of responsiveness, the effect size was calculated for the results at baseline and after treatment. [Results] The intrarater reliability was almost perfect (intraclass correlation coefficient = 0.93–0.97). The standard error of measurement and minimum-detectable-change were 0.70–0.66 and 1.62–1.53, respectively. The pressure pain threshold over the distal site was inadequately responsive in knee osteoarthritis, but the local site was responsive. The effect size was 0.70. [Conclusion] Algometry is reliable and responsive to assess measures of pressure pain threshold for evaluating pain patients with knee osteoarthritis.

Key words: Pressure pain threshold, Reliability, Responsiveness

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INTRODUCTION

Pain is inherently subjective, and pain measurement in patients with knee osteoarthritis (OA) relies primarily on self-reports¹⁾. The most common approaches to self-reported pain measurement are the use of a visual analog scale (VAS), numeric pain rating scales, and the Western Ontario and McMaster Osteoarthritis Index pain scale^{2–4)}. Although self-reported pain intensity is important, it is a composite of the physiological and psychological features of the patient and their health problem that is further mediated by social aspects, which can make it difficult to interpret responses^{5,6)}. Thus, objective pain measures are invaluable as they reflect different perspectives of the health condition. Therefore, measuring knee pain is an important component of clinical practice; its importance is evident in the frequency with which it drives healthcare utilization as well as its impact on quality of life⁷⁾.

An important step toward integrating pressure pain threshold (PPT) testing into routine clinical practice is the es-

tablishment of the reliability of viable instruments^{8,9)}. Such instruments must be commercially available, meet measurement standards under knee OA, and function under ideal conditions; furthermore, they must not be cost-prohibitive when used in a clinical setting. However, the clinimetrics of PPT testing with devices currently available in clinical practice are poorly understood for patients with knee OA.

Pain threshold is evaluated by methods including cuff algometry, pressure algometry, and algometry with electric stimulation^{8,9)}. Results in the literature suggest electronic and pressure algometers have comparable reliability^{10,11)}. Unfortunately, the costs of electronic pressure algometers limit their use in routine clinical practice. However, pressure algometers are inexpensive, more convenient, and more widely available¹²⁾. Moreover, pressure algometry methods can be used for clinical research to measure the efficacy of therapeutic interventions for the treatment of pain as well as general psychophysiological research⁸⁾.

The validity and reliability of self-rating scales such as the VAS for use in adults in general have been demonstrated¹³⁾. However, research on the reliability of experimental pain measurement tests is limited. Studies of PPT have preliminarily concluded that it is a valid and reliable pain measurement tool in patients with knee OA¹⁴⁾. However, the responsiveness, standard error of measurement (SEM), and minimum detectable change (MDC) have not been evaluated. Moreover, numerous studies in adults report differing intra- and interrater reliability of PPT among pa-

*Corresponding author. Ebru Kaya Mutlu (E-mail: fztebrukaya@hotmail.com)

thologies^{15, 16}). In addition, the intrarater reliability of PPT measurements in patients with knee OA has not been sufficiently demonstrated.

Therefore, this study aimed to establish the intrarater reliability and responsiveness of a clinically available algometer for patients with knee OA as well as to determine the MDC and SEM of testing to facilitate clinical interpretation of temporal changes.

SUBJECTS AND METHODS

Seventy-three patients (141 knees; mean age, 54.5 years; range, 40–69 years) with knee OA who received physical therapy for knee pain at Istanbul University, Faculty of Health Sciences, Division of Physiotherapy and Rehabilitation were included. Before the study, the patients completed an informed consent form that was approved by the Ethical Committee at Bakirkoy Dr. Sadi Konuk Education and Research Hospital (IRB study protocol: 201-146). The inclusion criterion was diagnosis of knee OA according to the American College of Rheumatology criteria and grade 2 or 3 knee OA according to the Kellgren and Lawrence (1957) scale^{17, 18}. The exclusion criteria were rheumatoid arthritis; history of knee or hip joint replacement surgery of the affected joint; history of any other surgical procedure on the lower limbs in the previous 6 months; a planned surgical procedure on the lower limbs in the next 6 months; the initiation of opioid analgesia, or corticosteroid or analgesic injection interventions for knee pain within the previous 3 months; and any physical therapy intervention on the lower limbs in the previous 6 months.

We analyzed variables including age, gender, symptom duration, and pain intensity. Mechanical pain was evaluated using an algometer. Pain intensity was assessed using a VAS in which the patient is asked to indicate his/her perceived pain during rest, activity, and nighttime; pain is scored from 0 to 10 on a numeric pain rating scale, with 0 indicating no pain and 10 indicating the worst pain possible¹⁹.

The patients ($n = 83$) attended 12 treatment sessions 3 times per week in the physical therapy clinic and underwent assessments before treatment and after 4 weeks of treatment. However, 10 patients did not complete the study (drop-out rate: 13.6%): 5 females and 1 male dropped out because of changes in their work situation, and the other 2 females and 2 males dropped out because of other health problems.

The Baseline 1200-304 (Push-Pull Force Gauge[®], Fabrication Enterprises, Inc.) is a handheld pressure algometer that responds linearly to force application between 0 and 10 kg (22 lb \times 0.25 lb and 10 kg \times 100 g); it has a 1-cm² round rubber tip, and values are displayed as the maximum force applied before the individual verbally states that the pain threshold has been reached.

The following standardized method was used when evaluating the patients' PPT. First, 1 PPT measurement trial was performed with the algometer on the hand to ensure the measurement procedure was understood; each patient was coached how to differentiate his or her report of tactile and painful stimuli. The PPT was recorded as the amount of pressure required to elicit a sensation of pain distinct from pressure or discomfort²⁰. We asked the patients to say

“stop” as soon as a discernible sensation of pain was felt; at this point, the algometer pressure was immediately released, and the plunger was retracted by the rater. The algometer probe was lowered at a constant rate of approximately 1 lb/s until the PPT was reached, as indicated by the patient's verbal notification. In the present study, the rater was a female physical therapist. All PPT measurements were applied by the same examiner, and the rate of algometric pressure application was constant to ensure good reliability.

The algometric measurements were performed while the patient was in the side-lying position according to the study by Moss et al²¹. The localization of the knee and ankle algometric pressure is easier with the patient lying on his/her side than in the supine position, especially in obese patients. In addition, holding the algometer vertically as opposed to horizontally is advantageous when applying the pressure²¹.

The PPT was subsequently assessed in all patients at 2 sites by one rater: the medial aspect of the patient's affected knee (approximately 1–2 cm mediolateral to the medial femoral tubercle) and the medial heel (approximately 1–2 cm lateral to the medial malleolus). These body sites were chosen, because they are painful and pain-free areas, respectively, in knee OA patients. With the patient lying on his/her side, a 1-cm² algometer probe was used to apply pressure to the skin at 90°²¹. The PPT was measured 3 times at each site on each side of the body, first starting at the ankle and then moving to the knee. Measurements were made approximately every 2 min. For consistency, the right side was tested first. Temperature, noise, and ambient lighting were kept as constant as possible throughout the testing sessions.

Walter et al.²² developed a robust mathematical approach for estimating the required number of patients for reliability studies. The hypothesis is that the test-retest reliability is lower than the interrater reliability for an estimated intraclass correlation coefficient (ICC) of 0.8 with a null hypothesis level set at 0.4. Using these parameters, a sample of 27 patients provides 80% statistical power with 95% confidence ($p < 0.05$). Concordantly, previous studies assessing the reliability of PPT in other pathologies have included between 13 and 70 patients^{11, 14, 16}. Therefore, a sample size of 70 knee OA patients was assumed adequate to assess the reliability of PPT in the present study.

All analyses were conducted using SPSS version 21. The level of significance was set at $p < 0.05$. Prior to determining statistical associations, the Kolmogorov-Smirnov test was performed to assess the distribution of data; all data were normally distributed. The data are expressed as means \pm standard deviations. The sample size adhered to the parameters and conditions governing parametric tests. Intragroup comparisons before and after treatment were performed by the paired t-test.

Many previous studies of the reliability of equipment-based measurements use Pearson correlation coefficients for statistical analysis²⁰. However, ICCs are arguably a more appropriate method for analyzing intrarater reliability²³. The calculation of 95% confidence intervals to identify the precision of the estimate is also recommended together with the SEM, which is a measure of the (im)precision of the measurements themselves^{24, 25}. Therefore, in the present study, ICCs were used to estimate intrarater reliability.

Table 1. Patient characteristics

	Before treatment (n=83)	After treatment (n=73)	
Gender (F/M)	62/11	55/8	-
Age (years)	55.5±6.7	56.24 ±6.7	-
BMI	31.5±4.9	31.39 ±5.1	-
Duration of symptoms (months)	8.1±10.6	7.6 ±10.7	-
VAS-rest	3.7 ±2.8	1.3 ±2.1	***
VAS-activity	7.8 ±2.2	4.7 ±2.9	***
VAS-night	5.2 ±3.7	1.8 ±3.03	***

Data are mean ± SD. BMI: body mass index; VAS: visual analogue scale

***p < 0.001, paired t-test

Table 2. Measures and intrarater reliability (ICC) of PPT testing using an algometer at each site in knee osteoarthritis

PPT-test (LBS)	Measure- Mean±SD			ICC Comparisons		
	Test 1	Test 2	Test 3	ICC _{1,2} (95%CI)	ICC _{2,3} (95%CI)	ICC _{1,3} (95%CI)
Before Treatment						
Medial malleol	7.65±2.79	7.38±2.62	7.48±2.70	0.93 (0.90–0.95)	0.97 (0.95–0.98)	0.94 (0.90–0.96)
Medial knee	5.54±2.97	5.41±3.10	5.46±3.01	0.95 (0.94–0.96)	0.97 (0.94–0.98)	0.96 (0.94–0.97)
After Treatment						
Medial malleol	8.19±2.69	8.24±2.7	8.18±2.66	0.97 (0.96–0.98)	0.97 (0.96–0.98)	0.98 (0.97–0.98)
Medial knee	7.51±2.92	7.55±3.01	7.68±3.06	0.96 (0.94–0.97)	0.97 (0.95–0.98)	0.96 (0.95–0.97)

Estimates of reliability were calculated using relative (i.e., ICC for absolute agreement) and absolute (i.e., SEM and MDC) estimates²³). Reliability coefficients were interpreted with the subjective categories of Landis and Koch²⁶) as follows: <0.40, 0.41–0.60, 0.61–0.80, and 0.81–1.00 correspond to unacceptable, moderate, substantial, and almost perfect agreement, respectively. A large ICC indicates that the test is objective and standardized²³). Error in the instrument or method would induce bias and low repeatability. The SEM, as an indicator of the expected measurement error in an individual's score using the same units as the algometer, was calculated as follows: $SD_{\text{pooled}} \times \sqrt{1 - ICC^{24}}$. The SEM represents the extent to which a patient's performance measurements vary if the test is repeated without any underlying change in the patient; in other words, it represents measurement error²⁴). The MDC was calculated at the 90% level, which is appropriate for assessing change during routine clinical use²⁵). The threshold amount of change in scores required for the rater to be 90% confident that true change exceeding the measurement error had occurred was determined by the following formula: $MDC_{90} = SEM \times \sqrt{2} \times 1.64^{27}$). The MDC indicates the amount of change required to exceed measurement variability²⁵); in other words, it represents the smallest change of an outcome measure that would be considered "real".

As a measure of responsiveness, the effect size was calculated for the results of the evaluations at baseline and after 4 weeks. To evaluate the changes due to physiotherapy, we used data from the patients who completed both evaluations. The effect size was calculated as the mean score difference divided by the standard deviation from the initial measurement as described by Kazis et al²⁸). An effect size >0.80 is

considered high.

RESULTS

The study patients ($n = 73$) were predominantly female (84.9%) and had a mean symptom duration of 8 months (Table 1). Pain (i.e., VAS-rest, VAS-activity, and VAS-night) significantly reduced after treatment ($p < 0.05$) (Table 1). The intrarater reliability between test sessions 1 and 2 before and after treatment on the medial knee were excellent ($ICC_{1-2} = 0.95$ and $ICC_{1-2} = 0.96$, respectively). The intrarater reliability was also excellent at both sites between testing times 1 and 3, and 2 and 3 (all $p < 0.001$) (Table 2). The SEM and MDC were 0.66 and 1.53 for the medial knee, and 0.70 and 1.62 for the medial malleolus, respectively (Table 3).

The mean PPTs at the medial malleolus and knee sites before treatment were 7.50 ± 2.66 and 5.47 ± 2.99 , respectively; those after treatment were 8.20 ± 2.67 and 7.58 ± 2.97 , respectively (Table 3). The effect size data are shown in Table 3.

DISCUSSION

The results of the present study suggest that PPT testing is reliable and acceptable irrespective of the presence of knee pain in the patient undergoing testing. The intrasession repeatability of a single PPT measurement taken by the same rater was excellent for both the knees and ankles in patients with knee OA. The absolute error, reflected by the SEM and MDC, indicates that the clinical measurement properties of the PPT evaluated in this study were appropriate. In addition, our findings show that the PPT is responsive to a physical

Table 3. Standard error of measurement (SEM), minimum detectable change (MDC), and effect size (ES) of PPT testing (Units: lb)

	Before treatment	After treatment	SEM	MDC	ES
	Measure- Mean (SD)	Measure- Mean (SD)			
Medial malleol	7.50±2.66	8.20±2.67	0.70	1.26	0.26
Medial knee	5.47±2.99	7.58±2.97	0.66	1.19	0.70

therapeutic intervention.

Our results are comparable to those of other investigations. Persson et al. report intrarater ICCs ranging from 0.70 to 0.90 for testing the upper trapezius muscles of 27 healthy female patients²⁹. Furthermore, Paungmali et al.¹⁵ performed PPT testing over the local lumbar area; their intrarater ICC of 0.99 is comparable to our ICC for the knee. Wessel¹⁴ reports that the reliability of pain threshold varies from 0.61 to 0.91 between repeated measurements in knee OA. Moreover, Wylde et al.³⁰ report no significant differences in the PPTs at any body site in OA patients between baseline and 1 week, with high or very high ICCs (0.83–0.91). In addition, Moss et al.²¹ report that the ICCs (95% confidence interval) for pilot data ($n = 5$) indicated reasonable intrasubject reliability for both knee PPT (ICC = 0.94 [0.55–0.99]) and heel PPT (ICC = 0.94 [0.59–0.99]). The present study found high reliability (ICC = 0.93–0.97) comparable to that in the previous studies. Therefore, our findings suggest that only one PPT measurement needs to be performed, because reliability of this protocol produced high ICCs for the same examiner.

Paungmali et al.¹⁵ report an SEM of 1.19 for testing over the local lumbar area of patients with low back pain; meanwhile, the SEM in the present study was 0.66. This suggests that the local lumbar area muscles may be a more labile site with respect to pain threshold than the knee. In the present study, the absolute error, reflected by the SEM and MDC, suggests that the clinical measurement properties were appropriate. Clinicians will be able to use these values in their communications with funders or other healthcare professionals to indicate their level of confidence in the extent and meaning of score changes in their patients. However, clinicians should note that the MDC at the knee site of 1.53 indicates that the tool may not be sufficiently accurate to detect a decrease in the PPT if the baseline value is smaller than the MDC, as was the case in patients with knee OA.

Physical therapy is effective for pain relief and improvement of quality of life in patients with knee OA³¹. However, the effect size is large, suggesting that the PPT is suitable for evaluating the effects of a physical therapeutic intervention²⁸. Walton et al.³² show that the PPT over the upper trapezius muscle is responsive and useful as part of a protocol to evaluate clinical changes. The results of the present study indicate that patients with knee OA who received physical therapy experienced clinically meaningful improvements in pain as evidenced by the effect sizes for pain. The effect size was moderate at 0.70, indicating the PPT is sufficiently sensitive for detecting changes over time.

Algometry is easy to perform in clinical settings⁹, as equipment, training, time, and physical space requirements are minimal. Algometry has been demonstrated to

be adequately reliable for research when high-precision instruments are used in healthy subjects or patients^{33–35}. However, Arendt-Nielsen et al.³⁶ and Neogi et al.³⁷ report that knee OA duration and radiographic findings are not associated with the PPT. On the other hand, Imamura et al.³⁸ and Lee et al.³⁹ demonstrate that OA patients have lower PPTs than controls across multiple body sites. Also, Wyle et al.³⁰ support the inclusion of pressure algometry in studies assessing pain perception abnormalities in OA. Thus, it can be concluded that the PPT can be used in research.

In adults, PPTs decrease with age⁴⁰, and females exhibit lower thresholds than males⁴¹. Age may also influence sensitivity to pressure pain independent of the disease progression, as evidenced by an increase in the PPT with age⁴². Other factors such as the patient's levels of anxiety and anticipation may affect response to pressure pain induced by a pressure algometer⁴³. In addition, studies of adults report experimenter gender and professional status may influence thresholds to pain stimuli^{44, 45}. In a study by Kallai et al.⁴⁴, 160 healthy participants were asked to immerse their hand in cold water (–1 °C) as long as possible. The participants tolerated pain longer when examined by a faculty member than when examined by a student. In addition, the participants expressed higher pain intensity when examined by a female rater. The present study was performed by professional rater, which is a strength of the study.

The major limitation of this study is that we could not assess interrater reliability, which is a critical measure for evaluating the PPT. Although the present study demonstrated the reliability and responsiveness of the PPT, these values should be corroborated by studies with larger populations. The second major limitation is that we selected only one pain-sensitive site from the knee joint area. In addition, we did not ask the patients if they perceived a decrease in their PPT. Therefore, additional studies are required to determine the minimum clinically important differences in the PPT in patients with knee OA.

The present study indicates that using algometry to measure the PPT is reliable and responsive, and can be used in patients with knee OA in clinical practice, especially in a single measurement session performed by a professional examiner.

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