Instrumental validity and intra/inter-rater reliability of a novel low-cost digital pressure algometer

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Background: Pain assessment is a key measure to accompany the treatment in a wide range of clinical settings. Low-cost valid and reliable pressure algometer (PA) would allow objective pressure pain assessment to a variety of health professionals. However, the PA is often expensive, which limits their daily use in both clinical settings and research. **Objectives:** The study aimed to assess the instrumental validity, the intra- and inter-rater reliability of an inexpensive digital adapted PA. **Methods:** A single rater applied random 60 compressions on a force platform and 98 random compressions on a laboratory load cell (LLC). The pressure pain thresholds (PPT) of 20 volunteers were collected twice (3 days apart) by 2 raters. The main outcome measures were the maximal peak force (in Kgf) and the PPT (PA vs. force platform; PA vs. load cell; rater-to-rater comparison). Chronbach's α test was used to assess internal consistency. The standard error of measurement (SEM) provided estimates of measurement error, and The Bland-Altman method estimated the measurement bias, with lower and upper limits of agreement. **Results:** No differences were observed comparing the compression results. The internal consistency was excellent, with low SEM values. Excellent correlations were found, with a low risk of bias for all measures. **Conclusion:** The results showed both the validity and reliability of PA. The results could potentially ensure and spread objective assessments of pressure pain threshold among clinicians. PA provides valid, intra- and inter-rater reliable measures of compressive force and PPT, respectively.

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Abstract

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Conclusion: The results showed both the validity and reliability of PA. The results could potentially ensure and spread objective assessments of pressure pain threshold among clinicians. PA provides valid, intra- and inter-rater reliable measures of compressive force and PPT, respectively.

Introduction

Pain is mostly assessed by patient self-report, using the visual analogical scale of pain.[1] Self-reported pain intensity is important and reflects one's physiological and psychological features. However, it can be difficult to interpret due to subjectivity and overestimation of pain level[2]. Objective assessment to evaluate pain is essential as a useful outcome evaluated by time or as a prognostic measure that can predict future outcomes.[1,3] The pressure pain threshold (PPT) has been used to assist in the diagnosis of pain providing a quantified force value of tissue tenderness.[4] The PPT occurs at the minimum transition point when the applied pressure is sensed as pain.[5] The Pressure algometer (PA) is an equipment used to assess PPT on both regional and widespread musculoskeletal pain.[6] The PA includes a system to convert the force applied through a 1-cm^2 pressure application surface and a display of readings in Newtons (N) or kilograms of force (Kgf). The PA enables the rater to objectively quantify the pain level and the recovery of underlying problems or soreness levels.[4]

Unfortunately, PA is often expensive, which limits their daily use in both clinical settings and research.

The adapted portable hanging scale (HS) may be a cost-effective alternative to ensure accurate PA assessments. The battery-operated equipment is used for weighting in a suspended way by using a load cell, which is a metallic sturdy element, yet elastic enough for a load to deform it. The load cell is attached to a strain gauge, which reads the electrical resistance change when a load is placed in the load cell. The change in electrical resistance is converted to a digital signal by the strain gauge, which is readable on the display.[7] The force platform is considered the gold

standard for measuring vertical and horizontal forces, such as vertical jump and postural balance.[8,9] Such valid property ensures the precision of data collection for compression.

A simple, readily available equipment to quantitatively measure pain in clinical practice routine is desirable, as the available devices are expensive for many clinicians, especially in low income and developing countries.[6] Therefore, the validation process of a low-cost PA would enable widespread quantitative measures of pressure pain thresholds in clinical practice routine.[4,9] Also, a low-cost, valid and reliable equipment would benefit early assessment of pain conditions in primary care in areas without expensive technologies to diagnose acute or chronic conditions.

The purpose of this study was to examine the instrumental validity, the intra- and inter-rater reliability of a low-cost PA, adapted from an HS. The validity was assessed by comparing differences in the measurements of a series of random peak force applied on a force platform and a laboratory load cell. The current hypothesis is that an inexpensive pressure algometer has validity and reliability enough to be considered as a standard equipment to assess pressure pain threshold.

Materials & Methods

Equipment

All data was collected at the facilities of the School Clinic of Physical Therapy – Federal University of Juiz de Fora in May 2019. The PA (MED.DOR Ltd., Brazil; maximum compression = 50 Kgf, the precision = 0.1 Kgf, 3 digits display) had a 5-cm screw attached to the distal extremity. A 1-cm^2 round rubber application surface was attached to follow the standardization for pressure algometry (Figure 1).

The two-axis force platform (37 cm × 37 cm; PASCO, Pasport PS-2142, Roseville, USA), collected data at a sample rate of 1,000 Hz using five force beams: four corner beams to measure the normal vertical force (ranging from −1,100 N to +4,400 N) and a fifth beam to measure the parallel force (ranging from −1,100 N to +1,100 N). The recorded trials were converted from N to Kgf, as 1 N = 0.101971621 Kgf.

The laboratory load cell – LLC (Miotec™ Biomedical Equipments, Porto Alegre, RS, Brazil; maximum tension-compression = 200 kgf, the precision = 0.1 kgf, the maximum error = measurement = 0.33%) was also used to collect compressive data. The conversion from analog to digital signals was performed by an A/D board (Miotec™, Biomedical Equipments) with 16-bit

resolution input range, a sampling frequency of 2 kHz, common rejection module greater than 100 dB, the signal-noise ratio less than 03 μV Root Mean Square and impedance of 109 Ω. All pieces of information were recorded and processed using the software Miotec Suite™ (Miotec™ Biomedical Equipments, Porto Alegre, RS, Brazil).

INSERT FIGURE 1 HERE

Procedures

Instrumental validity

An independent trained rater performed 60 random 3-s pressure trials with 3-s apart on the force platform. Data were collected and stored using the PASCO Capstone Software (Version 1.13.4, PASCO Scientific, 2019) and the adapted PA display readings were recorded through an off-board USB synchronized camera. The rater also performed 98 random 3-s pressure trials with 3-s apart on the top of the LLC fixed on a stable surface using a bench vise.

Intra- and inter-rater reliability

The middle Deltoid muscle's PPT of 20 participants (10 women; 22±2 years; 63±13 Kg; 160±10 cm; 23±4 Kg/cm^2) were collected twice (3 days apart – day 1 and 2) by 2 trained independent raters. The exclusion criteria included: IMC>28 kg/cm^2; any self-reported health issues; 5-day alcohol consumption before the assessments; shoulder pain; previous shoulder surgery or any diagnosed shoulder or cervical impairment. The objectives of the study were explained to the subjects, and they were notified of the benefits and potential risks involved before signing an informed consent form prior to participation. The Federal University of Juiz de Fora ethics committee for human investigation approved the procedures employed in the study (Reference number: 02599418.9.0000.5147). The 4-day training consisted of applying constant-progressive pressure with the adapted PA on the LLC with Miotec™ software for visual feedback (MioTrainer™, Biomedical Equipments, Porto Alegre, RS, Brazil) for 2 non-consecutive days (3 non-consecutive hours per day). Then, a third rater monitored the pressure for the other 2 consecutive days using the same software, but the raters in training did not receive any visual feedback.

To evaluate the intra- and inter-rater reliability, the participant remained seated with the trunk erect, feet on the floor and hands resting on the thighs. These sites received progressive 1 kg/s pressure controlled by a metronome until the participant experienced pain[4]. An effort was made to standardize the anatomic locations at each session. The same examiner was responsible for palpating and marking the PPT site on each subject before PPT measurements both on day 1 and day 2. The middle Deltoid's site was topographically determined in the middle of a horizontal line drawn between the acromioclavicular joint and the Deltoid muscle insertion.[10] Three measurements were performed for each site 10 to 15 seconds apart. Others authors did not consider the first obtained value to estimate the true PPT measurement.[11] Conversely, the first measure was excluded in the present study. The mean of the other two measures was used for analysis.[12]

The participant lifted the opposite hand when the PPT was achieved, i.e. when the applied pressure evoked pain. The examiner pressured the "tare" button to lock the reading, immediately retracting the PA. Then, the PPT reading was registered.[13]

Statistical analysis

The recorded peaks were extracted. All trials were used for analysis, consisting of a total: 1. Sixty measures (validity analysis - force platform vs. PA); 2. Ninety-eight measures (validity analysis - LLC vs. PA); 3. Eighty measures (reliability analysis). Data were presented as mean and standard deviation. The paired and independent Student's t-test was used to compare the intra- and inter-rater differences between measures, respectively. Significance was set at $p<0.05$. Intraclass correlation coefficients ($ICC_{1,1}$) were calculated to compare the results between both types of equipment. Chronbach's α test was used to assess the expected correlation of both types of equipment measuring the same construct. The standard error of measurement (SEM) was also calculated to provide an estimate of measurement error. A linear regression estimated the coefficient of correlation (r), the adjusted coefficient of determination (r^2). The Bland-Altman method estimated the measurement bias, with lower and upper limits of agreement between results. The statistics were performed using the JAMOVI software (JAMOVI project, version 0.9, 2018).

Results

Validity: Force platform vs. PA

No differences were observed in pressure trials between the PA (4.14±2.4 Kgf) and the force platform (4.43±2.44 Kgf; p=0.51). The $ICC_{1,1}$ and the Chronbach's α returned values of 0.98 and 0.99, respectively. The SEM returned a value of 0.005 Kgf, and the linear regression showed very good results (r=0.997; adjusted r^2=0.995; p=0.001). The Bland-Altman results showed high levels of agreement (Figure 2).

Validity: LLC vs. PA

No differences were observed in the pressure trials between the PA (3.78±0.9 Kgf) and the LLC (3.63±0.93 Kgf; p=0.25). The $ICC_{1,1}$ and the Chronbach's α returned values of 0.94 and 0.981, respectively. The SEM returned a value of 0.004 Kg, and the linear regression showed very good results (r=0.963; adjusted r^2=0.926; p=0.001). The Bland-Altman results showed high levels of agreement (Figure 2).

Intra- and Inter-rater reliability

The PPT from both raters showed very low variation over time (Rater 1: Day 1=1.79±0.62 Kgf, Day 2=2.07±0.75 Kgf; Rater 2: Day 1=2.1±0.65 Kgf, Day 2=2.10±0.73 Kgf). The intra-rater comparison showed no differences among measurements. The $ICC_{1,1}$ analysis returned very good values (Rater 1: $ICC_{1,1}$=0.77, and Chronbach's α=0.89; Rater 2: $ICC_{1,1}$=0.87, and Chronbach's α=0.94). The SEM values were low (Rater 1=0.02, and Rater 2=0.01), and very good values were also obtained in the linear regression analysis (Rater 1: r=0.83; adjusted r^2=0.68; Rater 2: r=0.89; adjusted r^2=0.79). The Bland-Altman results showed high levels of agreement (Figure 2). The Inter-rater reliability showed no differences among measurements: Day 1: p=0.14; Day 2: 0.45), with good results for reliability analysis (Day 1: $ICC_{1,1}$=0.67, and Chronbach's α=0.82; Day 2: $ICC_{1,1}$=0.76, and Chronbach's α=0.84). The SEM result showed very low value (Day 1: 0.04, and Day 2: 0.02 Kgf), and very good values on the linear regression analysis (Day 1: r=0.69; adjusted r^2=0.46, and Day 2: r=0.74; adjusted r^2=0.52). The Bland-Altman analysis showed acceptable levels of agreement (Figure 3).

INSERT FIGURE 3 HERE

Discussion

The results showed no differences in peak compressive force recorded from PA and the force platform. No differences were found comparing PA and LLC. These findings support the primary hypothesis, which contended that the isometric peak compression force for the PA would reach acceptable levels of validity. Therefore, PA seems to be an alternative to expensive equipment. Pain has been described as a multidimensional event, involving psychological and physical domains with different patterns depending on the PPT site and emotional state.[14] These characteristics may impair conclusions and lead to biased clinical reasoning regarding group pain patterns due to intra-group and longitudinal variability in subjects' co-morbidities and momentaneous emotional state. Nevertheless, physical assessment is essential to provide prospective data comparing the effects of intervention for pain management.[15–17] Pressure algometry is also important to diagnostics. Some musculoskeletal problems, as fibromyalgia include PPT as a key assessment to distinguish healthy individuals from those with fibromyalgia.[18,19] Neck pain, cranio-cervical headache, and temporomandibular disorders also include PPT as an important component for clinical reasoning about the level of severity, also influencing the treatment direction.[1,5,20] The validation procedure enables the PA for clinical assessments in a practice routine, which may directly impact in primary and ambulatory care of low-income and developing countries, by adding an objective and inexpensive tool to assess pressure pain.

Other studies have identified different factors to consider when evaluating PPT, such as gender and obesity.[21,22] A review of studies involving induced pain found a consistent pattern of women exhibiting greater pain sensitivity and a reduction in pain inhibition compared to men.[23] In addition, the characteristic of pain imposed is an important factor for these differences, since the type of pressure pain has one of the highest effect sizes in the pain report.[12,24] It is suggested that interactions between biological and psychosocial factors are responsible for these gender differences, but all studies indicate the need for additional research to elucidate the mechanisms that drive gender differences in pain responses.[21,23,24] The present study balanced the sample concerning gender factor. However, the current sample was chosen only for reliability analysis purposes. PPT as a clinical result is well established, but more studies should take into account sex differences to avoid bias in experimental protocols.[21]

The association between PPT and obesity was reported. Some studies suggest that in areas with additional subcutaneous fat, pain thresholds for electrical or pressure stimuli increase and pain sensitivity decreases in obese individuals.[22,25] Several studies have also shown biochemical changes in trigger points with higher levels of inflammatory mediators, catecholamines and cytokines in obese individuals.[26] Mechanical stretching of the skin in response to excess fat can lead to a decrease in the density of nociceptive fibers, and obesity is associated with the chemical inhibition of pain with an increase in β endorphin and endogenous opioid peptide.[22] The present study only included non-obese individuals to avoid any interpreting bias.

PPT was also significantly correlated with high-density lipoprotein cholesterol. A high PPT was also found among subjects with hyperglycemia and excessive alcohol consumption.[27] In the present study, no blood assessment was performed to exclude those factors. However, the sample was constituted by young adults, decreasing the chance of any important health issues. Additionally, exclusion criteria included previous excessive alcohol consumption.

Other protocols to assess pain, such as temporal summation (TS) also include the pressure algometry.[28] The TS is usually used to recognize central sensitization, an augmentation of responsiveness of central neurons to input from unimodal and polymodal receptors.[28,29] The outcome of the processes involved in central sensitization, often a characteristic of chronic conditions is an increased responsiveness to peripheral stimuli including the mechanical pressure.[28] Therefore, the PA combined with other measurements, such as subjective scales and validated questionnaires might provide a multidimensional overview of pain in several situations of both acute and chronic musculoskeletal conditions.

It is also important to note that no significant differences were found for intra/inter-rater reliability. The PPT in body sites other than Deltoid muscle must be assessed to ensure PA validity on those sites. However, we hypothesize they should not give any different results to direct assessment using the PA, as the standard deviation remained at very low values and the current results gave very good measures compared to the force platform, LLC and additional good reliability. In fact, the instrumental validity of an equipment's measures also ensures unbiased assessments.[30]

Previous studies showed acceptable levels of validity and reliability of other digital systems of algometry.[4,6] Balaguier et al.[31] found high reliability between all three measures at sites in the

lower back. Walton et al.[1] found high reliability between measures in the upper fibers of the trapezius. Waller et al.[32] found high intra and inter rater-reliability (ICC=0.81–0.99; ICC=0.92–0.95, respectively) using 5 research assistants each testing 20 pain-free subjects at the wrist, leg, cervical and lumbar spine. However, for clinical and ambulatory settings, the high cost and the user's interface would be an issue to obtain fast objective pain measurements, requiring both training and experience for adequate assessments. Considering its portability, easy assemblage, and the lower cost, the PA seems to be valid standard equipment for PPT assessment. The PA used in this study had a cost of USD 10.00, while standard digital equipment cost range from USD 600 to USD 1,000.00.

Therefore, the PA is a valid method to assess compression compared to a force platform. The portability, cost-effectiveness, and friendly user system provide an effective way to measure PPT.

Conclusions

The current hypothesis was that an inexpensive pressure algometer has validity and reliability enough to be considered as a standard equipment to assess pressure pain threshold. The results showed that the low-cost adapted pressure algometer is a valid tool to assess compression measurements, including the pressure pain threshold. Intra- and inter-rater reliability is warranted for the adapted pressure algometer. Pressure pain threshold low-cost assessment is possible using the adapted algometer. Future directions are including the assessment in clinical routine to spread the systematic evaluation of pressure pain. Further studies should consider other assessments such as temporal summation and conditioned modulated pain using the pressure algometer.

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Figure 1

Figure 1. Adapted pressure algometer – PA.

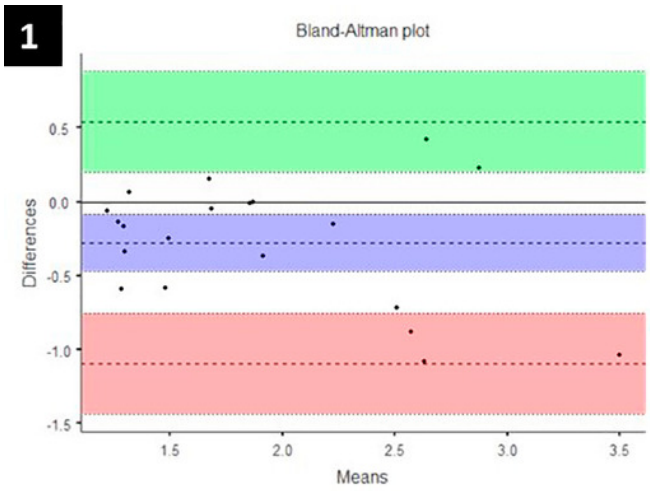
(1) Display; (2) On-Off button; (3) Tare button; (4) Unit selection button; (5) Adapted terminal.


1
2
3
4
5
ON/OFF
TARE
UNIT
0-10kg:d=5g
10-50kg:d=10g

Figure 2

Figure 2. Bland-Altman plot: Intra-rater reliability.

1) Rater 1: Bias = -0.27 (95% confidence interval [CI] = -0.47 to -0.08); lower limit of agreement (LLA) = -1.09 (95% CI = -1.43 to -0.75); upper limit of agreement (ULA) = 0.54 (95% CI = 0.20 to 0.88). 2) Rater 2: Bias = 0.09 (95% CI = -0.24 to 0.06); LLA = -0.72 (95% CI = -0.99 to -0.46); ULA = 0.54 (95% CI = 0.28 to 0.80). Inter-rater reliability. 3) Day 1: Bias = -0.21 (95% CI: -0.44 to 0.01); LLA = -1.18 (95% CI: -1.58 to -0.78); ULA = 0.75 (95% CI: 0.35 to 1.15). 4) Day 2: Bias = -0.02 (95% CI = -0.27 to 0.22); LLA = -1.08 (95% CI = -1.52 to -0.64); ULA = 1.03 (95% CI = 0.59 to 1.47).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Bland-Altman plot
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Means
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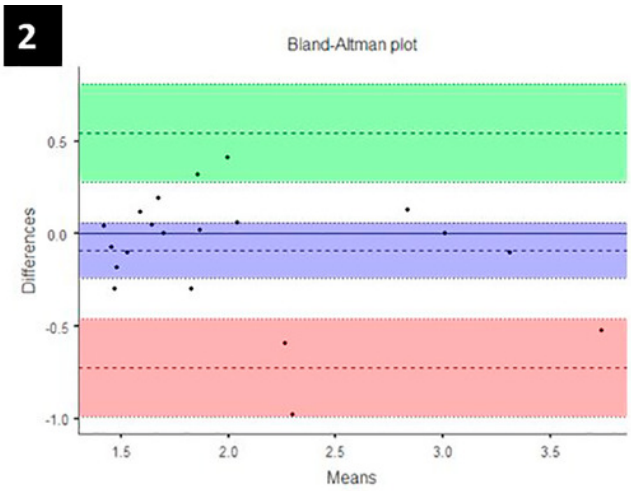
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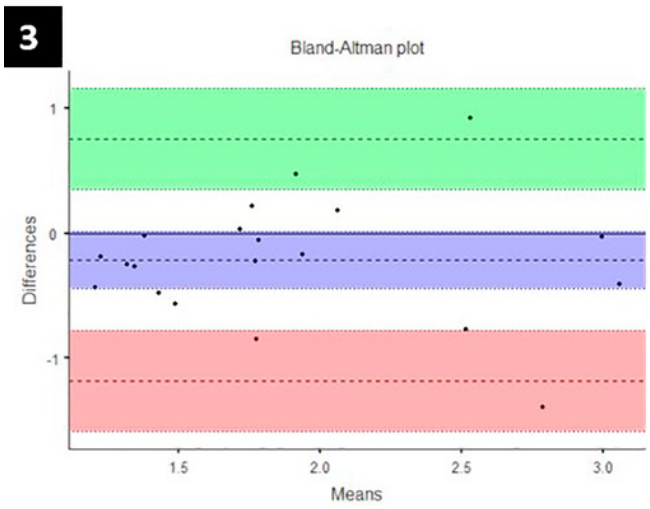
3.0
3.5


3
Bland-Altman plot
Differences
Means
1
0
-1
1.5
2.0
2.5
3.0

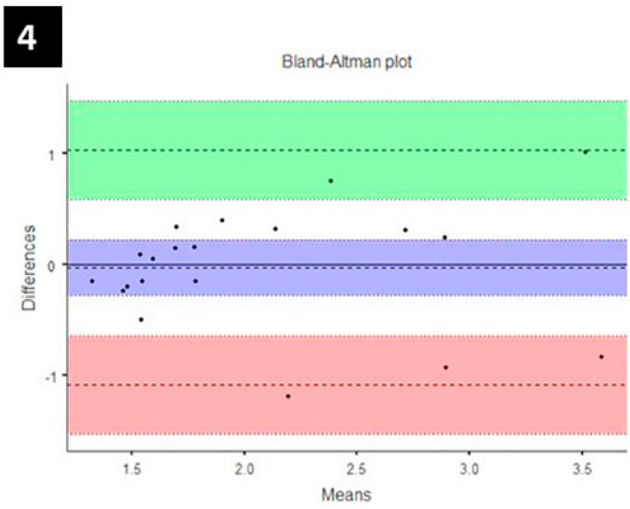

4
Bland-Altman plot
Differences
Means
1
0
-1
1.5
2.0
2.5
3.0
3.5

Figure 3

Figure 3. Bland-Altman plot: instrumental validity.

1) Force platform and PA. Bias = -0.29 (95% confidence interval [CI] = -0.33 to -0.24); lower limit of agreement (LLA) = -0.64 (95% CI = -0.72 to -0.56); upper limit of agreement (ULA) = 0.06 (95% CI = -0.01 to 0.14). 2) LLC and PA. Bias = 0.15 (95% CI = 0.09 to 0.20); LLA = -0.34 (95% CI = -0.43 to -0.25); ULA = 0.64 (95% CI = 0.55 to 0.73).