PRESSURE ALGOMETRY IS A USEFUL TOOL TO QUANTIFY THE PAIN IN THE MEDIAL PART OF THE KNEE: AN INTRA AND INTER RELIABILITY STUDY IN HEALTHY SUBJECTS.

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Running Title
Pressure Algometry utility in the knee
ABSTRACT

Purpose: Pain quantification is essential for diagnostic and pain monitoring purposes in disorders around the knee. Pressure algometry is a method described to determine pressure pain threshold (PPT) by applying controlled pressure to a given body point. The purpose of this study was to determine the reliability of this method when it was applied to the medial part of the proximal tibia metaphysis and to evaluate the PPT levels between genders.

Methods: Fifty healthy (mean age; 46.9) volunteers were recruited, 25 men and 25 women. Pressure algometry was applied to a 1cm²-probe area on the medial part of the knee by 2 raters. Intra- and interclass correlation (ICC) was obtained and differences between genders were evaluated. Bland-Altman plots were performed to evaluate the variability of the measures.

Results: The mean values of PPT obtained by rater 1 and 2 were 497.5 Kpa and 489 Kpa respectively. The intrarater reliability values (95% IC) for rater 1 and 2 were 0.97 (0.95-0.98) and 0.84 (0.73-0.90) respectively. With regard to interrater reliability, the ICC (95% IC) for the first measurement was 0.92 (0.87-0.95) and 0.86 (0.78-0.92) for the second one. Women showed significant lower values of PPT than men. The Bland-Altman plots showed excellent agreement.

Conclusions: Pressure algometry has excellent reliability when it is applied to the medial part of the proximal metaphysis of the tibia. Women have lower values of PTT than men. Furthermore, the high reliability of the PA in an individual volunteer makes it a more valuable tool for longitudinal assessment of a given patient than for comparison between them.

Level of evidence; Prospective study, Level 2

Keywords
algometry, pressure, pain, knee, threshold
INTRODUCTION

Quantification of the pain is essential for diagnostic and pain monitoring purposes. Tenderness is the major symptom of muscle-skeletal dysfunction and its accurate evaluation is important in the diagnostic procedure. In the clinical practice digital pressure palpation is normally used to locate and assess the pain. However, this method is difficult to quantify and standardize because of the different degrees of pressure applied by the same or different examiners as well as the subjective report of pain by the patient [1].

The Pressure Pain Threshold (PPT) is defined as the point at which a non-painful pressure stimulus turns into a painful pressure sensation. Pressure algometry (PA) is a method described to objectify this PPT. This technique is a well-known and well-validated method to induce acute experimental pain. Different studies have been published about using this tool to evaluate pain in different locations of the body and showed high levels of reliability. Furthermore, some other studies concluded that PA is a worthwhile tool in the diagnosis and treatment evaluation of different orthopaedic disorders [1-7].

With regard on the different orthopaedic procedures that can be applied to an arthritic or pre-arthritic knee, these are conditioned by objective data (radiology and different scores; WOMAC, KSS or Oxford score) as well as the pain referred. Until now the most objective tool and the gold standard method to quantify the pain is the Visual Analogue Scale (VAS). This score is very subjective depending on the patient and a high correlation with the PA has been observed in a previous study [8]. Nevertheless, it has been used by other authors for pre- and postoperative evaluation of pain at the medial side of the knee in patients undergoing valgus tibial osteotomy [9-13]. Given the need to better improve the method to quantify the tenderness, not only to consider the more accurate surgical option but also to monitor the pain [14, 15], it was considered the possibility to apply the PA in the knee orthopaedic disorders.

Our initial hypothesis was that PA is a reliable tool to quantify the pain when it is applied in the medial part of the knee. For this, the main objective of this study was to determine the reliability
of PA when it was applied on the medial part of the proximal tibia metaphysis. A second objective was to evaluate if there were differences in PPT at the medial side of the knee between men and women.

MATERIAL AND METHODS

Fifty healthy volunteers were recruited for this study. The inclusion criteria were: age ranging from 25 to 65 years, no history of lower limb, spine or pelvic fractures, the absence of skin disorders, peripheral neuropathies or vascular diseases. Patients who took painkillers for any reason in the previous week were also excluded. All volunteers were Caucasian and the mean age was 46.9 (28-63). The experimental procedure was explained and signed informed consent was obtained from each participant. The study was also evaluated and approved by the ethics committee of our institution with the registry number 2013/5058/I.

PPT was determined using a handheld electronic pressure algometer with a 1cm² probe area with an increasing of the pressure rate of 20 Kpa/s (Algometer, Somedic Sales, Hörby, Sweden). The pressure algometer consists of a “pistol” handle and a rod with a pressure-sensitive gauge strain at the tip. All the measurements were performed at 1cm distal from the medial knee joint line with the knee flexed at 90º (Figure 1). This location was chosen because it is the point usually used to evaluate the presence of pain in the medial part of the knee when considering a surgical procedure like a unicompartmental or total knee arthroplasty or a high tibial osteotomy.

PA was performed on the same day under quiet and non-stressful conditions. The tip of the algometer was positioned on this specific point. By pushing the algometer the force applied to the tibia gradually increased. The participants were not allowed to see the algometer display in any moment, and, as soon as the volunteers experienced a painful sensation, they said “stop”, the algometer was immediately released and the force (in Kpa) was read from the display.

Two trained raters were instructed in the application of algometry. To determine the value of
PPT we used the method described by Nussbaum et al. [16]. Both raters made 3 consecutive algometry applications at the prescribed rate of 20 KPa/s, 1 minute apart. The first measurement was considered as a trial and the final value of the PPT was calculated from the mean of the second and third measurements. The number of raters (2), the time elapsed between both measurements (3-4 hours) and the time between measurements per participant (10-20 minutes) were decided on with the purpose properly evaluating the device and avoiding potential disturbances of any clinical variation of the patient between measurements [1,17]. The protocol is summarized in Figure 2. Epidemiological data and measurements descriptions are shown in Table 1.

Statistical Analysis

Descriptive statistics was used for demographic data. The intra- and interclass coefficient correlation (ICC) values were assessed. In order to identify the precision of the estimate, the 95% of confidence interval (IC) was assessed. The ICC values were classified as follows: <0.4 indicated poor agreement; 0.4 to 0.75, moderate agreement; and >0.75, excellent agreement [18, 19]. Systematic error evaluation between measurements, raters and gender was assessed with paired the Student’s T test [20, 21]. P values less than 0.05 were considered statistically significant. Bland-Altman plots were performed in which differences between two consecutive PPT measurements and between the two raters were graphically represented [22]. All analysis and plots were performed with R3.0 (The R Project for Statistical Computing).

RESULTS

Fifty volunteers were finally assessed, 25 men and 25 women, with a mean age of 46.9 years (range 28-63, SD 10.7) (table 1). Pressure algometry was well tolerated by all the participants. The mean PPT obtained by the rater 1 and 2 was 497.5 Kpa and 489.0 Kpa respectively. The mean PPT obtained in the first measurement was 497.5 Kpa and in the second one 505.9 Kpa. The ICC values for both, inter and intra-rater reliability, was excellent give the ICC value (Table 2 and 3). Women showed significant lower values of PPT than men with mean values of PPT
387 Kpa and 616.2 Kpa respectively (Table 4). All values showed in tables 2, 3 and 4 presented an excellent correlation with the exception of women for the second measurement or when women were evaluated by the rater 2 (moderate correlation).

The values of the systematic error of evaluation translate the differences between both measurements for each volunteer. This systematic error was measured as mean and standard deviation. The fact that all p-values of the systematic error of evaluation were not significant (p>0.05) means that there is an absence of a systematic error in these measurements. Only in one measurement in table 4 the p-value obtained was <0.05.

The Bland-Altman plots for all the evaluations are included in the Figure 3 and illustrated the distribution of the different algometry values. This PPT ranged from 200 to 900 Kpa/cm² and it was found an excellent intra and inter-rater agreement.

DISCUSSION

The main finding of this study was that PA has an excellent inter and intra-rater reliability when the PPT is measured on the medial part of the proximal metaphysis of the tibia. Based on this, the hypothesis has been confirmed. These results confirmed that algometry might be a useful tool in objectifying pain in this part of the knee. Secondarily it was observed a higher PPT values for men. Different authors have studied the utility of this technique in different parts of the body. In the main, they concluded that the PA has a good agreement between observers. Farasyn et al. [23] studied the applicability of this method in patients with non-specific low back pain by applying a deep cross-friction pressure in the proximal gluteus region. They observed excellent inter- (ICC 0.97) and intrarater (ICC 0.98) reliability. Other authors also showed a good reliability for this technique in other parts of the body; the first dorsal interosseous muscle [1], the neck and head muscles [4, 6-7, 17, 24] or following a spinal manipulation [25].

Different studies have assessed the utility of PA with different disorders involving soft tissues of the knee. Van Wilgen et al [5] studied the reliability of this instrument in athletes with patellar
tendinopathy. They observed that the PTT of asymptomatic athletes differed from that of athletes with tendinopathy and showed excellent inter-rater (ICC 0.93) and moderate intra-rater (ICC 0.6) reliability. In this study, the authors placed the algometer on the distal apex of the patella for the control group and directly on the most painful spot of the patellar tendon in the group with tendinopathy. In a similar way, other authors evaluated the potential usefulness of the PA as a tool to evaluate and monitoring the clinical evolution of the pain at the medial side of the tibia in runners who suffered a tibial stress syndrome. They also found lower values of PPT in this specific population compared to a healthy group of volunteers and concluded that PA may be a useful tool to evaluate this painful syndrome [26]. On the other hand, Lunn et al [27] assessed the PPT levels in patients who had undergone a total knee arthroplasty. They observed significant higher PPT values during quadriceps contraction compared when the muscle was relaxed. It is a well-known phenomenon that active muscle contraction may increase the local value of the PPT [28-29].

In the study here presented, all measures were performed in a non-stressful condition and in a location (proximal metaphysis of the tibia) without any muscle disturbance. The fact of deciding on the medial metaphysis of the proximal tibia was due to, if the hypothesis was confirmed, the PA could be routinely applied in the decision-making protocol of the different therapeutic options around the knee. Furthermore, this point (1 cm distal to the joint line) is the one where we usually apply digital pressure to reproduce pain in the medial compartment of the knee when we have to decide between one of the different surgical options in pre-arthritic or arthritic knees.

Another interesting finding of this study was the significant lower values of PPT obtained in women compared with men. Previous studies have found similar results when PA was applied in other locations of the human body [30-31]. Fisher et al. in a study conducted in a healthy population found higher values of PPT in males in 8 out of 9 different muscle regions evaluated [32]. In a recent study, Aweid et al [26] analized the PTT in healthy runners in the medial part of the distal tibia. They also observed a lower PTT in females compared to males. The reasons to explain these findings are not well known, but different authors referred hormonal reasons as a possible explanation for these differences [33, 34].
The mean values obtained by the 2 raters ranged around 500 Kpa with a mean standard deviation around 200 Kpa. These results mean that exist an important variability of the PPT for the different healthy volunteers studied. However, as it is shown in the table 2 and 3, the low values of the systematic error measurement, mean that, despite this variability of the PTT between the volunteers studied, these values are constant for the same volunteer, independently of the number of measurements done or the rater involved in the measurement. For this, we consider that this tool may be more useful in monitoring pain in a patient before/after a given procedure than compare patients between them.

The algometer used in this study requires that the observer see the digital display during the measurement in order to increase the local pressure while maintaining a constant speed (20 Kpa/s). This fact means that the final value (in Kpa) is determined when the volunteer say “stop”, but this value is not blinded for the rater. This fact may be considered as a limitation of this study. By the other hand, although this study only considered healthy volunteers and the correlation between VAS and PA has been studied in a previous work [8], the fact of not comparing these 2 scores between them in this study could be considered as another limitation.

Conclusions
Pressure algometry has excellent intra- and interrater agreement when is applied on the medial part of the tibial metaphysis in a healthy subject. Women have a lower PTT levels at this location than men. Furthermore, the high reliability of the PA in an individual volunteer makes it a more valuable tool for longitudinal assessment of a given patient than for comparison between patients.

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22:1549-55.


TABLES AND FIGURES LEGENDS.

Figure 1. Algometry measurement procedure, location and method of use.

Figure 2. Protocol of measurements for both raters.

Figure 3. Bland-Altman plots shows distribution of data of each measurement and rater data.
Table 1. Epidemiological data and measurements description.

<table>
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<th>Number of participants</th>
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<td>Male: Female</td>
<td>25: 25</td>
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<tr>
<td>Mean age (range)</td>
<td>46.9 (28-63)</td>
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<tr>
<td>Std. Deviation</td>
<td>10.7</td>
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<tr>
<td>Number of measurements taken by each observer each time</td>
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<tr>
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<td>Interval between measurements per participant (minutes)</td>
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<td>Interval between two measurements (hours)</td>
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<tr>
<td>Total of measurements per observer</td>
<td>300</td>
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Table 2. Intra-rater agreement values. (*) Mean difference, in Kpa, between the first and second measurements (intra-rater), (**) Standard deviation of the mean differences.

<table>
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<tr>
<th>INTRA-RATER</th>
<th>AGREEMENT ICC (95% CI)</th>
<th>MEAN</th>
<th>SD</th>
<th>SYSTEMATIC ERROR EVALUATION</th>
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<tr>
<td></td>
<td></td>
<td>MEAN*</td>
<td>SD**</td>
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<tr>
<td>RATER 1</td>
<td>0.97 (0.95-0.98)</td>
<td>497.5</td>
<td>201.8</td>
<td>-8.4</td>
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<tr>
<td>RATER 2</td>
<td>0.84 (0.73 -0.90)</td>
<td>489.0</td>
<td>206.4</td>
<td>-3.8</td>
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Table 3. Inter-rater agreement values. (*) Mean difference, in Kpa, between the first and second measurements (intra-rater), (**) Standard deviation of the mean differences.

<table>
<thead>
<tr>
<th>INTER-RATER</th>
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<th>SD</th>
<th>SYSTEMATIC ERROR EVALUATION</th>
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<tr>
<td></td>
<td></td>
<td>MEAN</td>
<td>SD</td>
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<tr>
<td>MEASUREMENT 1</td>
<td>0.92 (0.87-0.95)</td>
<td>497.5</td>
<td>212.2</td>
<td>8.4</td>
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<td>MEASUREMENT 2</td>
<td>0.86 (0.73-0.9)</td>
<td>505.9</td>
<td>203.4</td>
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</table>
Table 4. Inter and intra-rater agreement values for both raters and both measurements divided on men and women. *p<0.05

<table>
<thead>
<tr>
<th></th>
<th>INTER-RATER CORRELATION</th>
<th>INTRA-RATER CORRELATION</th>
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<tbody>
<tr>
<td></td>
<td>ICC (95% CI)</td>
<td>Mean (Kpa)</td>
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<td><strong>First Measurement</strong></td>
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<tr>
<td>MEN</td>
<td>0.92 (0.82 - 0.96)</td>
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<td>WOMEN</td>
<td>0.86 (0.72 - 0.93)</td>
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<tr>
<td><strong>Second Measurement</strong></td>
<td></td>
<td></td>
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<tr>
<td>MEN</td>
<td>0.86 (0.71 - 0.93)</td>
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<tr>
<td>WOMEN</td>
<td>0.68 (0.40– 0.84)</td>
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