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DIAGNOSTIC METHODS: VALIDITY STUDY

Concurrent validity of pain scales in individuals with myofascial pain and fibromyalgia

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ABSTRACT

Objective: Clinicians and researchers often use the numeric pain rating scale (NPRS) and visual analog scale (VAS) to measure and track pain in individuals with myofascial pain syndrome (MPS) and fibromyalgia (FM). The VAS is often used as a reference standard in chronic pain research. To date, no studies have specifically measured the concurrent validity of the NPRS and VAS in these individuals. The purpose of this investigation was to determine the concurrent validity of the NPRS when compared to the reference standard VAS in patients with MPS and FM.
Methods: This investigation explored the concurrent validity of the NPRS and VAS in sixty participants with MPS (N = 30) and FM (N = 30). All participants underwent one day of testing using the American College of Rheumatology criteria for classifying FM. For each tender point (18-total), participants graded tenderness using the NPRS and VAS.
Results: An excellent relationship was found between the NPRS and VAS for the MPS group (rho≥0.81, 95% CI 0.79-0.85, $p < 0.001$) and the FM group (rho ≥0.96, 95% CI 0.92-0.97, $p < 0.001$).
Conclusion: The results of this study suggest that the NPRS has good concurrent validity with the referenced standard VAS among individuals with MPS and FM.

1. Introduction

Myofascial pain syndrome (MPS) and fibromyalgia (FM) are two chronic pain conditions characterized by soft tissue tenderness, fatigue, anxiety, sleep disturbances, and depression (Clauw and Crofford, 2003). It is estimated that up to 54% of women and 45% of men may suffer from MPS with the most common age range between 27 and 50 years (Kruse and Christiansen, 1992; Lavelle et al., 2007; Wright, 2000). It is also estimated that more that 5 million Americans have FM, with a higher presence among women ages 35–60 years (Clauw and Crofford, 2003; Lawrence et al., 2008). The most recent statistics, from 2012, showed that the total cost for treating chronic pain conditions ranged between $560 to $635 million annually in the United States (Gaskin and Richard, 2012).

MPS is often described as a regional condition with specific trigger points (TrPs) that can refer pain while FM is characterized by chronic widespread pain and local tender points(Gerwin, 2001). Researchers have found that the FM local tender points may also be active TrPs (Alonso-Blanco et al., 2011; Ge et al., 2009, 2010). Thus, individuals with FM may develop TrPs at the tender point sites that can refer pain (Ge, 2010; Ge et al., 2009; Gerwin, 2001). This research suggests a connection between the two conditions in which individuals with FM may also suffer from MPS or vice versa. Some researchers have postulated that FM may be concomitantly

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present in over 50% of patients diagnosed with MPS thus both pathologies may need to be considered during the examination process (Leblebici et al., 2007).

The diagnosis of MPS and FM is often dependent upon the findings from manual pressure palpation of tender points and trigger points since medical tests and imaging are often inconclusive (Ge et al., 2010; Perrot et al., 2008). For MPS, the standard TrPs examination uses the recommended criteria established by Simon and Travell (Bron et al., 2007; Simons and Simons, 1999). For FM, clinicians commonly use the 1990 American College of Rheumatology (ACR) criteria for classification of fibromyalgia (FM) (Wolfe et al., 1990). The 1990 ACR criteria include the following: history of widespread musculoskeletal pain for at least 3 months, bilateral axial pain that affects areas above and below the waist, and 11 out of 18 tender points. The tender point examination includes assessing 18 predetermined tender points along the neck, back, arms, and legs (Fig. 1) using pressure algometry (Wolfe et al., 1990). Researchers have begun to use the ACR criteria for examining both MPS and FM patients (Alonso-Blanco et al., 2011; Ge et al., 2009, 2010).

Clinicians and researcher will often use patient related outcome measures such as the numeric pain rating scale (NPRS) (Bigatti and Cronan, 2002; Ferraz et al., 1990; Hawker et al., 2011) and visual analog scale (VAS) (Ferraz et al., 1990; Hawker et al., 2011; Park et al., 2011) to measure and track a patient's progress. These outcome measures are commonly used in studies involving manual pressure palpation and algometry (Najm et al., 2003; Walton et al., 2011; Yoo, 2013). The ordinal 11-point NPRS (0-no pain, 10-most intense pain) is the most commonly used version which has good test-retest reliability (r = 0.79-0.96) in patients with chronic pain and rheumatic conditions (Downie et al., 1978; Ferraz et al., 1990; Hawker et al., 2011; Jensen and McFarland, 1993; Marques et al., 2008). The VAS is a continuous scale comprised of a 10 cm (100 mm) vertical or horizontal line between two end points. The VAS is often used as reference standard in chronic pain research (Hawker et al., 2011; Hjermstad et al., 2011). The VAS has good test-retest reliability (r = 0.94)(Hawker et al., 2011) and a strong association based on the intraclass correlation coefficient (ICC) = 0.86-0.95) with the NPRS in patients with rheumatic diseases (Downie et al., 1978; Ferraz et al., 1990; Hawker et al., 2011; Marques et al., 2008) and acute pain (r = 0.94)(Bahreini et al.; Bijur et al., 2003). Clinically, the NPRS may be good for individuals with chronic pain due to ease of use (e.g. reduced administrative burden) from the ordinal type format versus the more abstract VAS scale (Hawker et al., 2011; Hjermstad et al., 2011).

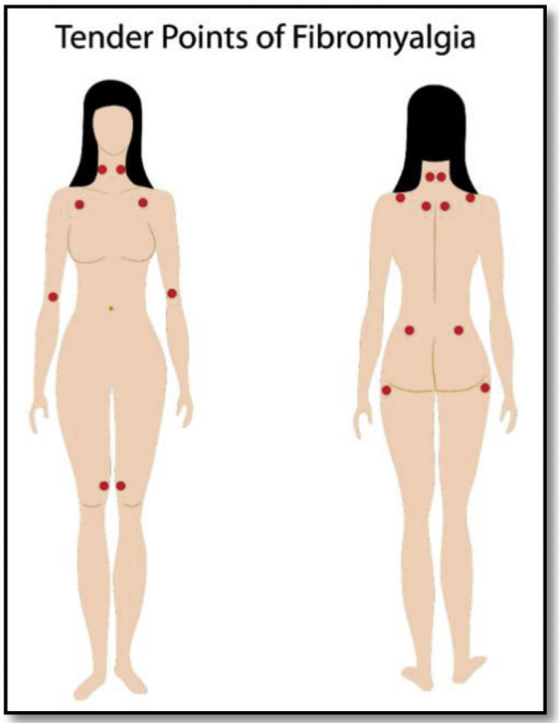

Fig. 1. ACR tender point criteria.

Both the NPRS and VAS are commonly used together to measure pain among individuals with MPS and FM. To the authors knowledge, no studies have specifically measured the concurrent validity of these outcome measures for these conditions. Prior studies have focused on measuring this relationship in individuals with rheumatic disease and acute pain (Bahreini et al.; Bijur et al., 2003; Downie et al., 1978; Ferraz et al., 1990; Hawker et al., 2011; Marques et al., 2008). Currently, there is a gap in our understanding of the performance of these two measures when used together for individuals with MPS and FM. Clinicians and researchers may be challenged when attempting to gauge the clinical course of a patient's pain when both measures are used. The purpose of this investigation was to determine the concurrent validity of the NPRS when compared to the reference standard VAS in patients with MPS and FM.

1.1. Study design

This investigation explored the concurrent validity of the NPRS and VAS in participants with MPS and FM. This study was approved by a University Institutional Review Board (IRB) (No. 15–116). All participants agreed and completed an approved consent before participating in this investigation. Data collection was conducted in the university kinesiology department laboratory.

1.2. Participants

Sixty participants (N = 60), from 2 groups, were recruited via convenience sampling from the local community, university campus, and local support groups in the Southern California area. Participants enrolled in this investigation were 18–65 years of age and met the inclusion criteria for 1 of the 2 groups. All participants were required to read, speak, and write English in order to complete the study related forms and consent. Each group consisted of 30 participants. The following inclusion criteria for each group was as follows: (1) *MPS group*: Individuals with a medical diagnosis of MPS that did not meet the 1990 ACR criteria for classifying FM. (2) *FM group*: Individuals with a medical diagnosis of FM based upon the 1990 ACR criteria. Exclusion criteria included: No integumentary injuries or musculoskeletal conditions at the predetermined palpation sites, neurologic, metabolic, or systemic conditions, connective tissue disorders, shingles or post-herpetic neuralgia, prior surgery that may affect ability to participate in the study, pacemaker or electrical implant that may be affected by electronic equipment, inability to tolerate testing duration and procedures, and medications that may alter a subject's sensation or affect their ability to participate in this study.

1.3. Study protocol

Prior to data collection, all participants filled out a questionnaire to provide demographic information and determine eligibility. All eligible participants were then given an IRB approved consent form

to review and sign. All participants underwent the same testing procedure by one investigator and were blinded from the examiner's scores and other participants enrolled in the study. Testing was conducted between the hours of 8 a.m. and 2 p.m. and participants were instructed to refrain from taking any medication (e.g. pain medication or muscle relaxants) that would interfere with outcomes prior to testing. Each participant was tested using the 1990 ACR criteria which includes testing 18 pre-determined tender point along the neck, back, arms, and legs using pressure algometry (see Fig. 1)(Wolfe et al., 1992). The algometry pressure was applied at a rate of 1 kg per second for a total of 4 s at each tender point up to a maximum of 4 kg/cm^2 of pressure (Okifuji et al., 1997; Wolfe et al., 1990).

1.4. Outcome measures and instruments

The 10 cm (100 mm) VAS and 11-point NPRS were simultaneously used to quantify the participants perceived level of pain at each tender point after palpation from the examiner. Both outcome measures have good test-retest reliability ($r \geq 0.79$) (Downie et al., 1978; Ferraz et al., 1990; Hawker et al., 2011; Marques et al., 2008) and a strong association (ICC = 0.86-0.95)(Downie et al., 1978; Ferraz et al., 1990; Hawker et al., 2011; Marques et al., 2008). The VAS was considered the reference standard for this investigation. The JTECH (Midvale, UT) Tracker Freedom® wireless algometer was used with the accompanying Tracker 5® software to measure the pressure at each predetermined tender point. The algometer was connected to the computer via Bluetooth® wireless technology. During testing, the software visually guided the examiner via feedback provided on the monitor. The Windows© based computer screen displayed a concurrent numeric reading of the amount of pressure being applied by the examiner in kilogram-force per square centimeter while the software recorded the session. The manufacturer reports an accuracy error of $< \pm 0.5\%$ (0.05 kg/cm^2) for this technology (Sterling, 2011). The 1990 ACR criteria are integrated into the Tracker 5® software allowing the examiner to test and monitor pressure at each tender point. Algometry is a valid and reliable tool that is commonly used in research involving individuals with MPS and FM (Nussbaum and Downes, 1998; Park et al., 2011; Persson et al., 2004). The reader is referred to the bibliography for further references on algometry.

1.5. Testing procedures

All recruited participants underwent 1 session of testing which lasted approximately 45 min. Participants were placed in a seated position on a plinth or chair during testing. If the participant was unable to sit for the time period, they were placed in a prone or sidelying position. A mirror was placed in front of the participant to monitor their facial expressions during testing. Prior to testing, the investigator demonstrated the procedure with each participant using 2 control points: left thumb and dorsum of the right forearm. This was done to familiarize the participant with the testing procedures, scoring the NPRS and VAS, and to answer any questions prior to testing. The control points were independent of the ACR pre-determined points (Okifuji et al., 1997).

During data collection, the investigator applied a gradual increasing pressure to each of the 18 pre-determined points using the computerized algometer, one time (Okifuji et al., 1997; Wolfe et al., 1990). The graded pressure was concurrently monitored on the computer screen for each tender point. The participant recorded their level of tenderness at each point using the NPRS and VAS once the examiner reached 4 kg/cm^2 of pressure or once a maximum level of pressure was felt. Participants were able to stop testing at any time by verbally telling the examiner. The algometer was calibrated prior to testing each participant.

1.6. Statistical analysis

Statistical calculations were conducted with SPSS v.22 (IBM SPSS, Chicago, IL). Prior to data collection, an *a priori* power analysis was conducted for a moderate effect size ($r = 0.30$) which yielded a sample size of $N = 57$ (Cohen, 1988; Copay et al., 2007). Participant descriptive data for age, body mass, height, and body mass index (BMI) was calculated for each group. Means, standard deviation, 95% confidence intervals (95% CI), and ranges of the ratio descriptive data from each group were calculated and presented in tabular format. Group differences were calculated using the independent *t*-test for continuous level data and the Mann Whitney *U* test for ordinal level data.

An ICC model 3, K statistic was used to calculate intrarater reliability. The criteria for evaluating the reliability coefficient was as follows: <0.75 = poor to moderate, ≥0.75 = good reliability (Portney and Watkins, 2009). Concurrent validity between the NPRS and VAS was calculated using the Spearman Rank correlation coefficient (95% limits of agreement). The criteria for evaluating the correlation coefficient was as follows: 0.00-0.25 = little or no relationship, 0.25-0.49 = fair relationship, 0.50-0.75 = moderate to good relationship, and values greater than 0.75 = excellent relationship (Portney and Watkins, 2009). Statistical significance was considered $p < 0.05$ for all measures.

1.7. Reliability testing

A pilot study was conducted to determine intrarater reliability of the testing procedure for this investigation. Ten independent participants with the conditions of MPS ($N = 5$) and FM ($n = 5$) were recruited. Participants underwent two testing sessions (45 min) within 1 week of each other which yielded good intrarater reliability (ICC model 3, $k = 0.92$). This coefficient is in accordance with the minimum threshold of ≥0.90 for ICC values postulated to be acceptable for clinical decision making (Portney and Watkins, 2009).

2. Results

Sixty participants aged 18–65 (mean 43.81 ± 14.59) years participated in the investigation and were included in the data analysis. There were no adverse events or participant dropouts during data collection. Statistical analysis revealed no significant differences ($p \geq 0.21$) between the MPS and FM groups for age, height, body mass, and BMI (see Table 1). For concurrent validity, an excellent relationship was found between the NPRS and VAS for the MPS group (rho≥0.81, 95% CI 0.79-0.85, $p < 0.001$) and the FM group (rho ≥0.96, 95% CI 0.92-0.97, $p < 0.001$) (see Table 2).

3. Discussion

The purpose of this investigation was to explore the concurrent validity of the NPRS with the referenced standard VAS in patients with MPS and FM. To the authors' knowledge, this is the first investigation to explore the concurrent validity of these pain measures in this population. The results of this investigation suggest that as a group the NPRS and VAS are comparable measures for individuals with MPS and FM.

Despite the strong statistical relationship found in this investigation, they may not be interchangeable among individuals with chronic pain. Prior research has revealed issues with the interscale interpretation of the measures in this population, thus efforts to determine a definitive interchangeability were not pursued (Aicher

Table 1
Participant demographics.

Characteristics (n)		MPS (30)	FM (30)	Comparison p-value
Sex	M/F	7/23	3/27	
Age (years)	Mean (SD)	43.6 (16.5)	46.4 (13.6)	0.42*
	95% CI	37.5–52.0	41.2–52.4	
	Range	18–65	22–65	
Height (m)	Mean (SD)	1.6 (0.1)	1.6 (0.08)	0.82*
	95% CI	1.6–1.7	1.6–1.7	
	Range	1.2–1.9	1.5–1.9	
Weight (kg)	Mean (SD)	82.2 (19.3)	80.1 (18.0)	0.37*
	95% CI	75.6–89.6	71.4–86.7	
	Range	51.2–133.8	51.2–127.0	
Body Mass Index (kg/m^2)	Median	29.0	28.7	0.21**
	95% CI	28.4–34.3	26.3–31.7	
	Range	20.7–61.0	19.0–43.9	

FM= Fibromyalgia; MPS = Myofascial Pain Syndrome; BMI = body mass index; n = number of subjects; M = male; F = female; SD = standard deviation; Group Comparison p-values: * Independent *t*-test; **Mann Whitney U.

Table 2
Concurrent validity of NPRS and VAS.

Group (n)	Spearman rho (rho)	95% CI	P-value
FM Group (30)	0.96	0.92–0.97	<0.001
MPS (30)	0.81	0.79–0.85	<0.001

NPRS-numeric pain rating scale; VAS- visual analog scale; p-value significant at $p < 0.05$.

et al., 2012; Kliger et al., 2015; Lund et al., 2005; Matamalas et al., 2010). Clinically, the NPRS may be good for individuals with chronic pain due to ease of use from the ordinal type format (Hawker et al., 2011; Hjermstad et al., 2011). However, it can be a challenge for patients to translate their subjective feeling of pain to a number which is an inherent limitation (Kliger et al., 2015). Due to this, the NPRS can be a challenge for patients with limited vocabulary, mentally challenged, children, and elderly individuals (Kliger et al., 2015). The VAS may be better for research due to its ratio measurement properties which often makes it the reference standard in studies measuring pain (Hjermstad et al., 2011). Parametric calculations can be used with the VAS versus the NPRS which requires a non-parametric statistic (Kersten et al., 2012; Price et al., 1983). The VAS is more challenging since patients must convert their perceived level of pain to an abstract scale (Kliger et al., 2015). Research has reported VAS failure rates of 7–16% with higher rates in handicapped, mentally challenged, patients on high doses of opioids, children, and elderly individuals (Brunelli et al., 2010; Hjermstad et al., 2011; Kliger et al., 2015; Mannion et al., 2007). Due to these limitations, clinicians should match the scale with the appropriate patient in order to achieve the most accurate measures and refrain from interchanging the scales.

It's important to note that both the NPRS and VAS are unidimensional measures of pain (Hjermstad et al., 2011). The subjective nature of these measures is an inherent weakness and is often influenced by the various dimensions of chronic pain (Hawker et al., 2011). Chronic pain is a multifaceted sensory and emotional experience that varies widely between individuals depending on the context and meaning of the pain and psychological state of the person (Crofford, 2015). A combination of biological, psychological, and social factors interacts to influence pain (Crofford, 2015). Clinician must consider these factors when using the NPRS and VAS as repeated measures in patients with MPS and FM.

3.1. Limitations

When considering the methodology and the results of this investigation, some limitations warrant discussion. First, MPS and FM were the only diagnoses studied which limits the generalizability of the investigation to these conditions and not to all the known chronic pain conditions. MPS and FM both require a manual pressure palpation examination as part of the diagnosis and are some of the most studied conditions among chronic pain pathologies (Croft et al., 1994; Ge, 2010; Myburgh et al., 2008; Queiroz, 2013). Second, standard manual palpation was not measured in this investigation. The algometer was used to concurrently measure the rate and amount of pressure that was applied during testing. Prior studies using standard manual palpation in this population have yielded variable results (Cott et al., 1992; Lucas et al., 2009; Myburgh et al., 2008). Third, a potential limitation of this investigation was age. The age of participants ranged from 18 to 65 (Mean 43.8) years. The results cannot be generalized outside of this age range. Despite this limitation, the study participants did represent the common age range for individuals diagnosed with MPS and FM as well as the average age of patients receiving care in outpatient physiotherapy clinics (Boissonnault and Fabio, 1996; Clauw and Crofford, 2003; Kruse and Christiansen, 1992; Lavelle et al., 2007; Lawrence et al., 2008; Wright, 2000). Fourth, the clinical course of individuals with chronic pain disorders such as MPS and FM needs to be considered. Often times, these individuals may feel different levels of musculoskeletal pain or symptoms on different days. Variations in a patient's perceived pain is a confounding variable in this population and must be considered when interpreting the results of the research (Bendtsen et al., 1996; Lachaine et al., 2010).

3.2. Future research

Future investigations should focus on validating these measures for other chronic pain conditions (e.g. chronic fatigue syndrome) in order to confirm their full utility. Future investigations should also examine the test-retest ability of these measures in the chronic pain population. As mentioned above, the daily symptom variability of chronic pain patients makes it difficult to monitor progress supporting the need for a consistent and stable measure (Bendtsen et al., 1996; Lachaine et al., 2010). Last, the efficacy of these measures with standard manual palpation needs to be investigated. The instruments used for this investigation may not be available in all clinical settings. Manual pressure palpation may have produced different results than the algometer.

4. Conclusion

The results of this study suggest that the NPRS has good

concurrent validity with the referenced standard VAS in individuals with MPS and FM. Despite the strong statistical relationship, prior research suggests that these measures may not be interchangeable in this population. Further research is needed to validate these claims. Thus, clinicians should match the scale with the appropriate patient in order to achieve the most accurate measures. As a group, they are both effective measures of pain in individuals with MPS and FM.

Clinical trial registration

ClinicalTrials.gov registration No. NCT02802202.

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IRB approval

California State University Dominguez Hills University Institutional Review Board (IRB) (No. 15–116).

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