Influence of expectations plus mobilization with movement in patient with lateral epicondylalgia: a pilot randomized controlled trial

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The aim of this study was to determine the influence of expectations plus mobilization with movement (MWM) in kinesiophobia, perceived disability and sensorimotor variables in patients with lateral epicondylalgia. A pilot randomized controlled trial in 24 patients with lateral epicondylalgia was conducted. Perceived pain, pain-free grip strength, pressure pain detection threshold, kinesiophobia measured with the short version of Tampa Scale of Kinesiophobia, perceived disability of the upper limb measured with disability of the arm, hand and shoulder questionnaire, and perceived disability specifically for the elbow joint measured with patient-rating tennis elbow evaluation, and also satisfaction were assessed. Participants were randomized to receive written instructions in order to create positive expectations regarding the technique in one group (n = 12) or neutral expectations in the other one (n = 12). All patients were treated for three sessions with the MWM technique. Measures were recorded before and after treatment. The effect size was calculated by Rosenthal “r” for nonparametrical tests. There were no significant statistical differences (P > 0.05) between groups after receiving the treatment for none of the physical analyzed variables. The Wilcoxon test showed statistically significant changes in kinesiophobia (Z = -2.278, r = 0.47, P = 0.023) and perceived disability (Z = -2.934, r = 0.61, P = 0.003) within positive expectations group. In conclusion this pilot study shows that a positive expectation almost given in a sealed envelope before treatment plus MWM produced changes in kinesiophobia and perceived disability in the immediate term, in patients with lateral epicondylalgia.

Keywords: Tennis elbow, Musculoskeletal manipulations, Placebo effect, Musculoskeletal pain

INTRODUCTION

Tennis elbow also known as lateral epicondylalgia is defined as pain in or near the lateral humeral epicondyle or in the forearm extensor muscle mass as a result of unusual strain according medical subject headings. It affects between 1% and 3% of the general population, and up to 15% of workers who perform repetitive gripping tasks with high loads (Bot et al., 2005; Roquelaure et al., 2006). It is more common in subjects between 45 and 56 years, in the dominant arm, and without distinction of the sex (Shiri et al., 2006). The average length of an episode is between 6 and 24 months (Smidt et al., 2006). Lateral epicondylalgia is a chronic pathology with a great impact in the society (Coombes et al., 2009).

Currently, the scientific evidence indicates that the mobilization with movement (MWM) technic is effective in the management of this condition in the short and long term, because it improves the patient function and decreases pain immediately compared to other treatment modalities and placebo (Bisset et al., 2006; Heiser et al., 2013; Herd and Meserve, 2008; Mulligan, 2006).
Though it is considered an effective technique and used by physical therapist regularly, the mechanism of action is unknown (Vicenzino et al., 2007). Biomechanical changes that may occur with the technique are transient and therefore they do not justify the changes in the patient clinical status (Hsieh et al., 2002). Similar to other manual therapy techniques, the effect of this kind of treatment is attributed to neurophysiological effects (Vicenzino et al., 2007). Bialosky et al. (2009) proposes a model where he explains this effects with changes that take place peripherally, at the spinal cord and supraspinal centers. Within these mechanism occurring at the supraspinal level could be the placebo effect (Bialosky et al., 2011). Despite the popular belief, placebo effect is a neurophysiological response and is associated with the activation of areas of the cortex related to pain modulation, emotions and cognitive assessment, and the activation of descending inhibitory pathways (Bialosky et al., 2011).

The exact mechanism that activate the placebo effect are not completely known, but it seems that some psychological factors as conditioning are involved, which has been the prevailing paradigm to explain the genesis of the unconscious placebo response (Colloca and Miller, 2011; Montgomery and Kirsch, 1997) and expectations (Bialosky et al., 2011). Although there is no universally accepted definition, expectations related to health are defined as the general belief that a clinical outcome will occur, being it positive, neutral or negative (Bialosky et al., 2011). Although various studies suggest that the amount of analgesia mediated with placebo effect is related to the previous expectations of the subject, there are few studies related to common physical therapy manual techniques (Bialosky et al., 2014, Bialosky et al., 2008; Rodríguez-López and López-de-Uralde-Villanueva, 2015) and none of them related to lateral epicondylalgia.

The aim of this study was to determine the influence of expectations plus MWM in kinesiophobia, disability and sensorimotor variables in patients with lateral epicondylalgia.

**MATERIALS AND METHODS**

**Design**

A pilot study was performed, with a randomized controlled trial design. The consolidated standards for reporting of trials (CONSORT) statement checklist for reporting parallel group randomized trials was conducted to strengthen this study (Schulz et al., 2010). As recommended by CONSORT guidelines, Fig. 1 presents a flow diagram for this trial (Schulz et al., 2010).

The study was carried out in two Health Centers of Primary
Care in the Community of Madrid, Spain. It was approved by the Southeast Local Research Commission of the Madrid Health Service (Code 22/14, Act 08/2014) and the Ethics Committee of Clinical Research of the Hospital Universitario La Paz (PI-1900). This study was registered in ClinicalTrials.gov with the identification number NCT02396550.

Selection criteria

Patients diagnosed with lateral epicondylalgia who were referred to the Physical Therapy Service by the General Practitioner were informed verbally and with an information sheet about the study, and those that agreed to participate signed a written consent. The inclusion criteria for the study were: (a) diagnosis of lateral epicondylalgia, (b) age between 18 and 65 years, (c) tenderness in the palpation of the lateral epicondyle, and pain in gripping tasks. The exclusion criteria were: (a) diagnosis of cervical radiculopathy, fractures or other bone disease of the upper extremity, paresthesia in the elbow, previous elbow surgery or bilateral symptoms, (b) patients with diabetes, hemophilia, cancer, osteoporosis or cardiovascular diseases, (c) patients who had received any type of injection in the elbow in the last 6 months, (d) patients who had received manual or physical therapy in the last 6 months.

Procedures

Sociodemographic data (name, age, sex, profession) and other data such as time of evolution of the pathology, dominant hand, affected side and drug taking, was collected before intervention. Once signed the informed consent and inclusion and exclusion criteria were passed patients were randomized into two groups: the first group was provided with a positive expectation by reading a sentence in a sealed envelope with this exact words (in Spanish): “The technique that you will receive is very effective for the treatment of lateral epicondylalgia, so we expect that it will reduce your perception of pain”. The second group was provided with a neutral expectation by reading the following sentence in a sealed envelope: “The technique that you will receive is used to treat lateral epicondylalgia, but its effect in pain perception is unknown”. Randomization was made by a third investigator who did not participated in the assessment nor the treatment using GraphPad software ver. 5.01 (GraphPad Software Inc., La Jolla, CA, USA).

After the expectations manipulation, the two groups received the same manual therapy technique, consisting in MWM of the elbow (described below) for three sessions spaced at least 48 hr, always in a similar climate, place and time. Both groups received MWM of the elbow, based in the previous studies were this technique was demonstrated effective in the treatment of lateral epicondylalgia (Paungmali et al., 2003; Vicenzino et al., 2001). As proposed by McDowell et al. (2014) for the standardization of the registration in the application of MWM, the technique that we used follows this annotation: “sup lyelblatgl MWM res gripx6sec” (Herd and Meserve, 2008). This translates as: with the patient in supine, the therapist applies a lateral glide as the accessory movement while the patient performs a gripping task using the dynamometer keeping it for 6 sec and repeating the technique for 10 times (Fig. 2).

Description of outcome variables

Pressure-pain detection threshold was measured using a pressure algometer (Wagner FDK 16, Wagner Instruments, Greenwich, CT, USA) since it has been proven to be a reliable and valid measure in lateral epicondylalgia (Coombes et al., 2012; Fernández-Carnero et al., 2009; Fernández-de-Las-Peñas et al., 2010). Measurement was performed in the epicondyle of the affect side. To improve accuracy each measurement was performed three times and we took the average.

Pain-free grip strength is a common measure in lateral epicondylalgia studies and is valid and sensitive to detect changes in patients with this pathology (Paungmali et al., 2003; Vicenzino et al., 2001). We used a hand dynamometer (JAMAR 5030J1, Patterson Medical Co., Warrenville, IL, USA). The measurement was performed before and immediately after the manual therapy intervention in the first and last sessions.

Perceived pain intensity at baseline and at the end of treatment was measured with a visual analogue scale from 0 to 100 mm

Fig. 2. Mobilization with movement procedure performed at the elbow.
Data analysis

Data analysis was performed with IBM SPSS Statistics ver. 22.0 (IBM Co., Armonk, NY, USA). Nonparametric tests were used due to the Shapiro–Wilk Test showed that variable data distribution was not normal and sample size was not sufficient to be supported by the central limit theorem (Mouri, 2013; Nixon et al., 2010). Descriptive statistics were generated in each group separately and, on one hand median and interquartile range were presented for quantitative variables, and on the other hand, absolute frequency and percentage were shown for qualitative, nominal variables.

The Fisher exact test was used to verify similarities for control variables as sex, elbow pain side, dominant side of the body and drug intake, and the Mann–Whitney U-test for quantitative variables at baseline. The Mann–Whitney U-test was used for the outcome variables comparison between groups. The Wilcoxon test for dependent samples was used for verifying the differences between variables from baseline to end of treatment. To get the effect size for nonparametric tests, was used Rosenthal “r” (Field, 2005) calculated as:

\[
 r = \frac{Z}{\sqrt{N}}
\]

Rosenthal “r” is interpreted as small \((r = 0.1)\), medium \((r = 0.3)\), and large \((r = 0.5)\) (Rosenthal, 1991).

All statistical tests were performed taking into account a 95% confidence interval and considering an outcome as statistically significant if \(P\)-value < 0.05.

RESULTS

Sample description

Twenty-six subjects were recruited between February 2015 and January 2016, two decline to participate. Twenty-four were randomly distributes in two groups, positive expectations group \((n = 12)\) and neutral expectation group \((n = 12)\).

The Fisher exact test did not show statistically significant differences between groups for the variables sex, elbow pain side, drugs intake, and dominant side of the body as shown in Table 1. The Mann–Whitney U-test did not show statistically significant differences between groups either for the quantitative variables age, pain duration, upper limb disability, kinesiophobia, perceived pain, expected pain after treatment, and for the pain-free grip strength tests. Statistically significant differences were found for pressure–pain detection threshold at the elbow (Table 1).

Between-groups comparison

The Mann–Whitney U-test showed no statistically significant differences between groups after the intervention for none of the measured variables (Table 2).

Intragroup comparison

The Wilcoxon test for paired samples showed statistically significant changes in kinesiophobia \((Z = -2.278, r = 0.67, P = 0.023)\) and in PRTEE \((Z = -2.934, r = 0.47, P = 0.003)\) in the positive expectations group when baseline and end-of-treatment values were compared. There were no statistically significant differences for
Manipulation of expectations and satisfaction

The manipulation of expectations was estimated by comparing the expected pain before and after the manipulation. The Wilcoxon test for paired samples showed statistically significant differences for the positive expectation group ($P = 0.04$) but not in the neutral expectation group ($P = 0.06$). The patient satisfaction with treatment was $7.08 \pm 2.38$ points in the positive expectation group and $8.08 \pm 1.83$ points in the other group.

DISCUSSION

The main goal of the study was to determine whether the expectations of the patient with lateral epicondylalgia could impact in kinesiophobia, disability, and sensorimotor variables after the application of the MWM technique described by Mulligan (1995). According to our knowledge, currently there are published only few papers about the influence of expectations in the application of a rehabilitation technique (Bialosky et al., 2008; Bialosky et al., 2014; Rodríguez-López and López-de-Uralde-Villanueva, 2015). This study is the first to evaluate this influence on the results of treatment by MWM of the elbow in lateral epicondylalgia. In contrary to present study, where it has been used MWM techniques and assessed sensorimotor and psychological variables, these previous studies (Bialosky et al., 2008; Bialosky et al., 2014; Rodríguez-López and López-de-Uralde-Villanueva, 2015) used high velocity low amplitude (HVLA) techniques and evaluated only sensorimotor variables. We consider our treatment technique could be neutral than HVLA, due to the known place-
bo effect of the sound of this approach that it could influences in the patient expectations (Bialosky et al., 2010). On the other hand, despite previous studies used negative expectation, we tried to avoid the use of them due to our sample were patients with lateral epicondylalgia, nor healthy subjects, and in the previous studies, authors demonstrated higher perceived pain in negative expectation group. We considered this practice could generate an ethical conflict over painful patients.

**Kinesiophobia and perceived disability**

Regarding kinesiophobia, although we did not found any differences between groups, within positive expectation group it was observed clinically relevant differences (Woby et al., 2005). This outcome could be due to the positive expectation over self-efficacy (Söderlund and Asenlöf, 2010). Likewise, self-efficacy improves patient’s capacity to generate new active coping strategies to reduce kinesiophobia. Recent studies had informed the mediating role of self-efficacy over expectations, and between pain intensity and perceived disability in patients with pain (Söderlund and Asenlöf, 2010).

Kinesiophobia is a complex construct involving different areas of the brain, especially related to the limbic system such as the amygdala (Meier et al., 2016). There is a large body of knowledge that relates this fear with the development of avoidance behaviors as described in the fear-avoidance model proposed several years ago by Vlaeyen and Linton (2000). Based on this model it could be assumed that patients with more kinesiophobia could perceive more disability and vice-versa. This could be the reason why in our study, those patients who reduced kinesiophobia, also perceived less disability at the elbow joint. Moreover, this outcome may be enhanced with the active movement component of the MWM technique applied.

**Sensorimotor variables**

No differences were found between and within groups in elbow PPDT, hand grip and pain intensity variables. Despite our results did not show statistical significance, it should be noted that the positive expectation group shows a $P$-value equal to the statistical level of significance selected, therefore with a clear trend towards significance. Also, this result is enforced by the moderate effect size obtained for this variable. This effect has been reported in previous studies were some authors found that MWM is an effective technique for the treatment of lateral epicondylalgia at the pressure-pain detection threshold. However, most of the available literature does not match with our results, in relation to pain-free grip strength and perceived pain. Paungmali et al. (2003) in their study, in which, a group of patients who received this technique is compared with another group who received a placebo technique and with a control group, after only one session of MWM, the authors found significant changes in pressure-pain threshold measured on the affected epicondyly, as well as in pain-free grip strength. Moreover, Vicenzino et al. (2001) after comparing three groups similar to those mentioned before, obtained significant changes in pain-free grip strength as well as a tendency towards improvement in pressure-pain threshold after three sessions consisting in the same technique. Abbott et al. (2001), in a preliminary study with just one group, after only one session of MWM found an improvement in perceived pain with movement, pain-free grip strength and maximum grip strength. There are various studies in which MWM is combined with different types of therapy (Amro et al., 2010; Bisset et al., 2006; Manchanda and Grover, 2008). Although the improvement found cannot be attributed only to MWM, it seems that in those groups in which this technique was used, better results were observed. One more difference between those studies and ours is the sample size collected. Therefore, we consider that a bigger sample size should solve this situation in the significance direction for those variables.

**Manipulation of expectations and satisfaction**

In our study we found significant changes in the expected pain after treatment in the positive expectation group but not in the neutral expectation one. It is remarkable that just with a simple written text there is an influence in patient expectations. We used a closed envelope with a written text inside which patients read in order to standardize the intervention and to avoid the influence of other factors as tone of voice or nonverbal communication. Another fact to be taken into account is that our physiotherapy treatment was extended during three sessions in a period of a week and the manipulation of expectation was done only in the first session.

Regarding satisfaction, in our study we have not found significant differences between the two groups. Satisfaction is slightly higher in the neutral expectations group. However, although there is no difference in the perceived pain, satisfaction is high in both groups (positive expectation: 7.08 ± 2.38, neutral expectation: 8.08 ± 1.83). Although there has been a greater improvement in the positive expectations group, satisfaction is higher in the neutral expectation group. Sometimes, creating a bigger expectancy could facilitate the emergence of a frustration associated with treatment, or at least the expectancy was bigger in relation to the information received. The authors consider that this issue is
necessary to take into account for not to generate too high expectancy in the clinical environment, or to establish difficult to arise outcomes with patients. Also we believe that the meaning of this situation could be that the neutral expectation group had a lower expectation for the treatment, and therefore they have been more satisfied at the end.

Clinical implications

From the results of this study also emerges the need to use active coping strategies such as MWM were the patients take an active part in treatment facilitating their commitment to their own illness. Understanding that the manual therapy mechanisms are complex and are not only related to the biomechanical effects (Bialosky et al., 2009), we believe it is important to physical therapists understand that placebo effect is an important mechanism in the treatment of lateral epicondylalgia patients, and in all those patients with musculoskeletal pathologies in general, since it can influence on perceived pain, disability or kinesiophobia. Therefore, instead of thinking it is an irrelevant mechanism, it is necessary to take placebo effect into account as part of our treatment, such as Bialosky proposed (Bialosky et al., 2011) we can handle the placebo effect by the input mechanism of positive expectations.

Other interesting point is the fact that despite receiving the same intervention, the positive expectations group has been less satisfied. This seems to indicate that is important managing patient expectations in an adequate manner, because unrealistic expectations with the treatment could lead to a lower satisfaction. In addition, as we discussed before we only tried to manipulate expectations by reading a sentence but in the clinical context there are many more variables (i.e., tone of voice, nonverbal communication, or treatment room) that may influence in the patient expectations, therefore it is probably easier to generate positive expectations.

Limitations

This study arises several limitations. The major limitation of the study was the sample size although the aim of this paper was to perform a pilot study to calculate the necessary data size to perform a posterior study. Our results showed no statistically significant differences in majority of the variables studied but we believe this was due to the small sample analyzed and if we would increase the sample, the results could change. Another potential limitation seems to be the fact that reading a single sentence placed in a sealed envelope may be not enough to generate positive expectations in patients longer than the immediate term, perhaps because the treatments were carried out in three different sessions, and the expectation were only induced before the first treatment. Maybe if we had reinforced expectations over the three treatment sessions the results could be different. Other important limitation to take into account, is related to the symptom evolution time and chronicity of the condition. At the present study there were included patients with pain since 1 to 12 months of duration, and this could limit the validity of the results for acute or chronic patients, on an independent way. According the perceived disability, DASH is a questionnaire thought to evaluate the upper limb disability, so it may not be sensitive enough to detect changes in patients with lateral epicondylalgia, and we thought that with a specific tool for lateral epicondylalgia we could detect those possible changes. The PRTEE has shown good psychometric properties to assess the perceived disability specifically in tennis elbow patients (Rompe et al., 2007), but the cross-cultural adaptation and validation in Spanish language hasn’t been published yet, that is why we choose to include as variable for the perceived disability at the elbow a nonpublished validated version of the PRTEE, in spite of the possible limitation of the results in our study. Also it is important to take into account that we found statistical differences between groups at the baseline in the pressure-pain detection threshold, and this could influence the result of this variable.

In conclusion this pilot study shows that a positive expectation almost given in a sealed envelope before treatment plus MWM produced changes in kinesiophobia and perceived disability in the immediate term, in patients with lateral epicondylalgia.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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Martínez-Cervera FV, et al. • Expectations plus MWM in lateral epicondylalgia

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