

Placebo effect on muscle pain. A brief study on patient predisposition and expectations

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ABSTRACT

Brief study that analyzes the placebo effect on acute muscle pain in adult patients belonging to a Peruvian medical center. Thus, in the form of a topical agent, petrolate jelly is compared to a pharmacologically active agent (diclofenac 1%). **Objectives:** To check that the initial muscle pain level of adult patients is decreased after the application of a placebo. **Methodology:** An ad hoc instrument "Rapid Pain Assessment" was used with which a pre and post-test evaluation was performed, following a double-blind design. **Results:** A final sample of 20 subjects (10 men and 10 women) was counted on, with an average age of 43. The overall proportion of improvement for the placebo group shows that 9 out of 10 patients showed some kind of improvement in their muscle condition, as well as for the group with the pharmacological agent. However, the levels of relief after the application of diclofenac 1%, show greater stability and higher percentages of improvement. **Conclusions:** The improvement in muscle pain in the placebo group is considered to be related to their predisposition and expectation about treatment. In any case, the exploration of these phenomena with more representative samples is suggested.

RESUMEN

Estudio breve que analiza el efecto de un placebo en el dolor muscular agudo de pacientes adultos pertenecientes a centro médico peruano. Así, bajo la forma de un agente tópico, la jalea de petrolado (vaselina) es comparada con un agente farmacológicamente activo (diclofenaco 1%). **Objetivos:** Determinar el grado de la disminución del dolor inicial de los pacientes tras la aplicación de un placebo. **Metodología:** Se empleó el instrumento ad hoc "Valoración Rápida del Dolor" para realizar una evaluación pre y post test, siguiendo un diseño a doble ciego. **Resultados:** Se contó con una muestra final de 20 sujetos (10 hombres y 10 mujeres), con una media de 43 años de edad. La proporción de mejoría para el grupo placebo muestra que 9 de 10 pacientes manifestó algún tipo de mejoría para el padecimiento muscular; al igual que el grupo con el agente farmacológico. Sin embargo, los niveles de alivio tras la aplicación de diclofenaco 1%, muestran mayor estabilidad y porcentajes más altos de mejoría. **Conclusiones:** Se considera que la mejoría del dolor muscular en el grupo placebo, se relaciona con la predisposición y la expectativa que tenían los pacientes acerca del tratamiento. Se sugiere la exploración de estos fenómenos con muestras más representativas.

Keywords

Placebo, muscle pain, predisposition, expectations.

assessment of a condition, but taking it to the background when it comes to the intervention.

Introduction

Muscle pain is a type of condition of common presence; usually cases are taken as consequences of a muscle overload. However, these ailments are also attributed as the effect of psychic variants. Despite this, psychology is considered as a cause or reactive of the phenomenon but not as part of its treatment. It is, to a certain extent, contradictory, to include psychological aspects for the

Therefore, placebo is found, understood as that "inert substance that can produce a healing effect in the patient" [1] (Figure 1). Silva [2] mentioned "changes that are often physiologically demonstrable, produced in the body as a result of a psychological stimulus induced by the administration of an inert substance, leading to decreased symptoms", due to the perception that patients are receiving some type of therapeutic intervention.

Table 1: Explanatory models of the placebo effect.

<i>Expectations</i>	<i>Reflection</i>	<i>Opioid</i>
Special type of cognition, which patients have regarding medical elements, knowledge of the therapeutic agent, administration, treatment, etc., which in themselves are linked to the placebo effect [14]	Under this theory a variety of substances, procedures, people or places, associated with effective treatments can function as conditioning stimuli for people's health [15].	Consider the endogenous release of opioid peptides (endorphins and enkephalins) into the central nervous system. However, the biochemical mechanism causing the placebo effect is not entirely clear.

Control gate theory

Melzack, Katz & Jeans [8], this theory introduces psychological variables in an attempt to explain why two individuals in the same situation have different experiences of pain, identifying personal and situational issues in the face of the perception and intensity of this phenomenon. They also mention the existence of neurophysiological mechanisms responsible for modulating the transmission of afferent nerve impulses, which would come to function as "gates" of impulses interpreted as pain.

In this same line are Amigo, Fernández y Pérez [9], who suggests that the neural activity of the nociceptors is modulated in the dorsal pole of the spinal cord, which acts as a gate that allows or prevents the passage of nerve impulses coming from the nociceptors and cortex. Thus, the "gates" increases or decreases the transmission of nerve impulses based on the activity of afferent sensory fibers and the descending influences of the central areas of the cortex.

That is, the perception of pain is not influenced only by messages reaching the brain from the body's specialized receptors, but is also modulated by descending messages from the brain that can, under certain circumstances, increase, attenuate or even block these messages (Table 2).

Table 2: Control gate theory.

<i>Dimension</i>	<i>Gate opening</i>	<i>Gate closure</i>
Physical	Physical organic discomfort..	Medication/physical stimulation.
Cognitive	Thought that converges in pain.	Varied thinking, in phenomena other than pain.
Affective	Negative emotions.	Optimism and happiness.

Methodology

For data collection, the "ad hoc" test "Rapid Pain Assessment" (R.P.A.) was used, instrument designed to assess: location, intensity, impact on daily functions, emotional interference, agents and magnitude in pain relief; it has an expert validity of .85 and reliability of .75 with Cronbach Alpha.

A double-blind design was followed for the assignment of topics, which had the same presentation (diclofenac 1% and petrolate jelly) and a similar visual appearance to each other. Thus, a day before the first visit the R.P.A. was used, as well as a day after the last application of the topics. On the other hand, to have greater control of the quantity, shape and veracity in the application of the topics, home visits were made to each patient.

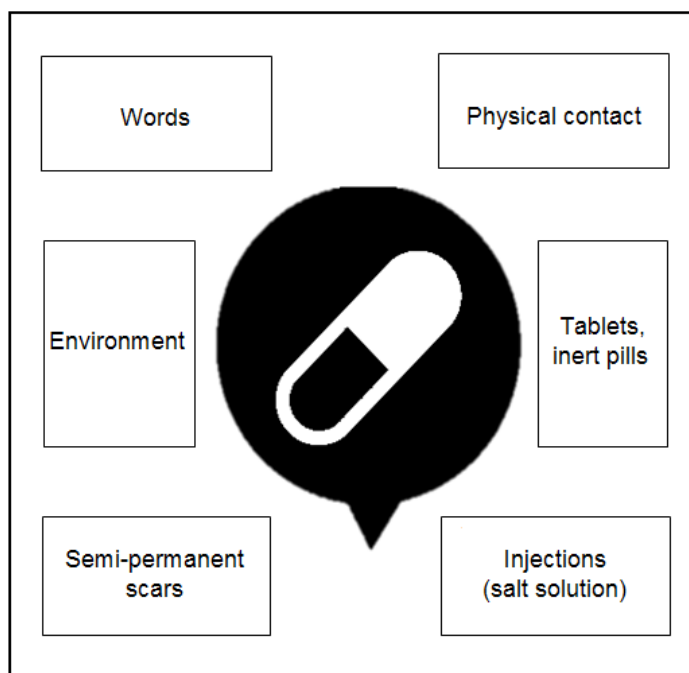


Figure 1: Presentation of placebos.

The existence of placebo is not a fortuitous event, much less recent, Cosacov [3] mentions that "is known long before the advent of experimental medicine, where a lot of treatments were placebo, and although doctors were already aware of it, they did not recognize this fact". Certainly, the things that could be offered at the time were reduced and the doctor's professional self-esteem could be put in question.

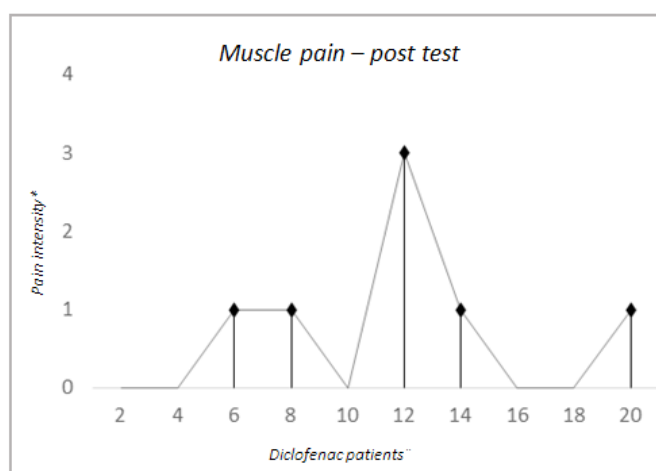
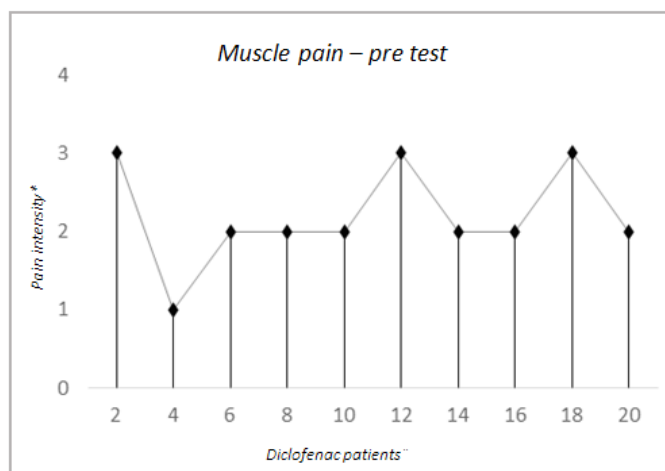
Currently, despite recent research on placebo, "one of the biggest mistakes in medical science has been made: dismiss its effect and mechanisms of action" [4]. "The Psychology itself has been postponing the inclusion of placebo evidence in its treatments" [5]. However, it is shared just like Otero, Munive, Escorcía & Ayala [6], that placebo is fundamental to the study of clinical psychology because "would allow us to understand the internal mechanisms of psychotherapy and its true scope."

Hence it was intended to contribute to this disjunction, through an experimental project carried out with a sample of 20 patients with muscle pain, in order to finally show the foundations of mind-body relationships, generating a vision of the disease from a multidisciplinary point of view and not only restricted to classical medicine, and offering a more prominence and active window for psychology in certain types of diseases, based on well-known theoretical approaches to the placebo effect.

Explanatory models of the placebo effect

Papakostas & Daras [7], propose the following three models that are taken as theoretical support for research (Table 1).

Pharmacological agent

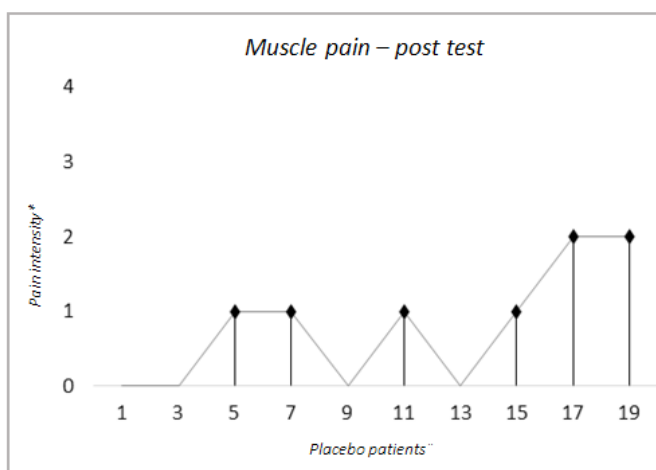
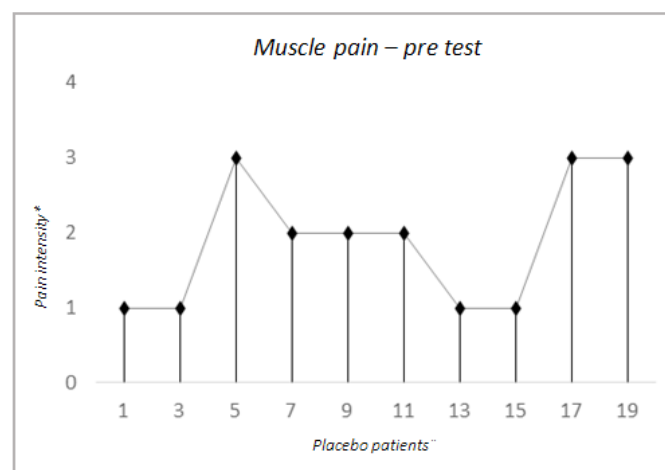


*Patients for the diclofenac group were encoded as even numbers

**Pain intensity follows the scale: 0= minimal pain; 1= mild pain; 2= moderate pain; 3= severe pain; 4= intolerable pain

Figure 2: Results - Pharmacological agent.

Placebo



*Patients for the placebo group were coded as odd numbers

**Pain intensity follows the scale: 0= minimal pain; 1= mild pain; 2= moderate pain; 3= severe pain; 4= intolerable pain

Figure 3: Results – Placebo.

Finally, the SPSS v.23 statistical program was used for data analysis and Wilcoxon testing to assess improvement in both groups (therapeutic agent vs placebo).

Ethical aspects

Research approvals issued by the medical facility concerned were obtained. All participants signed informed consent, their participation in this study was voluntary, confidential and without any invasive intervention beyond a topical application.

Results

Initially, 29 patients, with an average age of 43 years, were concentrated, of whom 20 (10 males and 10 women) exceeded the exclusion criteria: presence of psychiatric history or substance abuse, visual perception problems, therapeutic group assistants in the last month. The subjects were randomly and proportionately distributed to form the experimental (diclofenac 1%) and control group (petrolate jelly).

After recidivist application of ointments for five days, initial muscle pain levels are decreased in both groups, obtaining the proportions,

detailed below: 9/10 patients with the use of placebo and 9/10 patients with the use of diclofenac 1%. As for the distribution of recovery levels, the pharmacological agent (diclofenac 1%) found: 10% of the sample does not express any recovery, 30% achieved an improvement of 50%, 30% relief of 75% and the remaining 30% experienced a total restoration (Figure 2). On the other hand, placebo (petrolate jelly) obtained: 10% of the sample does not express any improvement, 20% obtained a recovery of 25%, 30% a relief of 50%, 10% a recovery of 75% and 30% remaining a full recovery (Figure 3).

Thus, the levels eased after the application of diclofenac 1%, show greater stability and higher percentages of improvement. In addition, 1/10 remaining patients in each group showed no significant improvement, that is, they were indifferent to treatment. On the other hand, when analyzing the values of the placebo group, it was found that the more consistent the higher the level of pain.

Discussions

Results contrast with improvements previously reported in other types of conditions, Nazario [10], showed improvement against flatulent symptomatology above 36.67% in the placebo group. On the other hand, the meta-analysis by Silva [11], in terms of the treatment of moderate or severe depressions, notes that the level of improvement in drug use versus placebo is minimal, indicating that regardless of the clinical study being conducted, it may be reduced but not eliminated the placebo improvement response.

It was mentioned by Melzack, Katz & Jeans [8], the opening of the "gates" and experience of pain, is influenced by physical dimensions but also by cognitive and affective components, which can modulate the transmission of nerve impulses. Bergado [12] states that psychological issues condition and influence the biological aspects, highlighting the particularities of the expectations and how they cause unique responses at the level of each organism. For this study, in the placebo group people with more acute pains have greater willingness and expectation for a new treatment, compared to those with mild pain.

On the other hand, Castillo, Gónzales & Rodríguez [13] when using placebos to improve athletic performance, noticed that using "innovative devices", whose action had no real effect on the performance of athletes, produced better results in matches. However, the limitations of this study focus on a reduced sample, suggesting research with greater scope, which may include other pharmacological agents and new placebo presentations. Naturally, following the ethical principles necessary for each case.

Conclusions

The pharmacological action of any agent is not intended to undermine, the results corroborate its effect on patients who were subjected. This study shows that a placebo can generate relief in certain types of conditions, such as acute muscle pain.

Thus, placebo, regardless of its pharmacological inertia, can generate an effect against muscle-type conditions. Clearly to a different extent to specific pharmacological agents, but with very suggestive rates that highlight their analgesic role, as a possible result of the predisposition and expectations of the participants in this study.

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