REME • Rev Min Enferm. 2020;24:e-1350
DOI: 10.5935/1415.2762.20200087

RESEARCH

VALIDATION OF A LASER AURICULOTHERAPY PROTOCOL FOR CHRONIC SPINAL PAIN

VALIDAÇÃO DE UM PROTOCOLO DE AURICULOTERAPIA COM LASER PARA DOR CRÔNICA NA COLUNA VERTEBRAL

VALIDACIÓN DE UN PROTOCOLO DE AURICULOTERAPIA LÁSER PARA EL DOLOR CRÓNICO EN LA COLUMNA VERTEBRAL

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Funding: *Conselho Nacional de Desenvolvimento Científico e Tecnológico* – CNPq (grant number: 4438262018). *Coordenação de Aperfeiçoamento de Pessoal de Nível Superior* – Brazil – CAPES – Finance Code 001.

Submitted on: 2020/07/06
Approved on: 2020/11/05

Responsible Editors:
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ABSTRACT

Objective: to validate a laser auriculotherapy protocol for chronic spinal pain. **Method:** methodological study carried from a systematic review based on the PRISMA Statement; content validation carried out by 21 specialists and pilot test with clinical validation of the protocol developed in people with pain. **Results:** from the analysis of 13 articles, a positive effect of acupuncture on pain relief was noted and it was possible to develop the following protocol: laser auriculotherapy, in 5 sessions, with the proportion of one session a week, bilateral application with alternation of the auricular pavilion at *Shenmen* points, Kidney, Sympathetic Nervous System, Urinary Bladder, Liver, Subcortex and Cervical, Thoracic and/or Lumbar Vertebrae, depending on the location of the pain. The evaluation of this content, assuming a level of agreement of 80% interobserver, resulted in the approval of all items in the protocol. In the clinical evaluation, when it was administered in people with spinal pain, the protocol developed showed a reduction in the pain average, an improvement in the tolerance threshold and a reduction in the pain impact on daily activities. **Conclusion:** the auricular acupuncture, carried out using an infrared low-level laser, in the studied protocol, proved to be capable of effectively treating chronic spinal pain.

Keywords: Acupuncture, Ear; Chronic Pain; Spine; Rehabilitation; Systematic Review.

RESUMO

Objetivo: *validar um protocolo de auriculoterapia com laser para dor crônica na coluna vertebral.* ***Método:*** *estudo metodológico realizado a partir de uma revisão sistemática, baseada no PRISMA Statement; validação de conteúdo por 21 experts e validação clínica do protocolo desenvolvido em pessoas com dor.* ***Resultados:*** *a partir da análise de 13 artigos foi observado o efeito positivo da acupuntura no alívio da dor e foi possível construir o seguinte protocolo: auriculoterapia com laser, em cinco sessões, com a proporção de uma sessão por semana, aplicação bilateral com alternância do pavilhão auricular nos pontos Shenmen, rim, simpático, bexiga, fígado, subcórtex e vértebras cervical, torácica e/ou lombar, dependendo do local da dor. A avaliação desse conteúdo assumindo nível de concordância de 80% interavaliadores resultou em aprovação de todos os itens do protocolo. Na avaliação clínica, ao ser administrado em pessoas com dor na coluna vertebral, o protocolo desenvolvido demonstrou reduzir a média de dor, aumentar o limiar de tolerância e diminuir o impacto da dor nas atividades de vida diária.* ***Conclusão:*** *a acupuntura auricular, realizada com laser de baixa potência infravermelho no protocolo estudado, provou ser capaz de tratar com efetividade a dor crônica na coluna vertebral.*

Palavras-chave: *Acupuntura Auricular; Dor Crônica; Coluna Vertebral; Reabilitação; Revisão Sistemática.*

How to cite this article:
Nassif MS, Iunes DH, Sousa L, Costa ICP, Oliveira PE, Moura CC, Menezes FS, Mantuani APA, Chaves ECL. Validation of a laser auriculotherapy protocol for chronic spinal pain. REME - Rev Min Enferm. 2020[cited _____ ___ __];24:e-1350.Available from: _____ DOI: 10.5935/1415.2762.20200087

RESUMEN

Objetivo: *validar un protocolo de auriculoterapia láser para el dolor crónico en la columna vertebral.* ***Método:*** *estudio metodológico realizado a partir de una revisión sistemática, en base a la declaración PRISMA; validación de contenido por 21 expertos y validación clínica del protocolo de tratamiento en personas con dolor.* ***Resultados:*** *del análisis de 13 artículos se observó el efecto positivo de la acupuntura en el alivio del dolor y se pudo construir el siguiente protocolo: auriculoterapia láser, en cinco sesiones, con una sesión por semana, aplicación bilateral con alternancia de pabellón auricular en los puntos Shen Men, Riñón, Nervio simpático, Vejiga, Hígado, Subcórtex y vértebras cervicales, torácicas y / o lumbares, dependiendo de la localización del dolor. La evaluación de este contenido, asumiendo un nivel de acuerdo del 80% entre evaluadores, resultó en la aprobación de todos los ítems del protocolo. En la evaluación clínica, cuando se administró a personas con dolor en la columna, el protocolo de tratamiento demostró reducir el promedio de dolor, aumentar el umbral de tolerancia y disminuir el impacto del dolor en las actividades de la vida diaria.* ***Conclusión:*** *la acupuntura auricular, realizada con láser infrarrojo de baja potencia en el protocolo estudiado, demostró ser capaz de tratar eficazmente el dolor crónico de columna vertebral.*

Palabras clave: *Acupuntura Auricular; Dolor Crónico; Columna Vertebral; Rehabilitación; Revisión Sistemática.*

INTRODUCTION

Approximately 9% to 12% people (632 million) experience back pain at any given time and almost a quarter of them (23,2%) claim to have suffered for about a month.[1] These back pains generally start occurring around 20 to 40 years of age, predominantly affecting the economically active population.[2]

It is highlighted that the three osteomuscular conditions most commonly associated to the spine (cervical, thoracic and lumbar) are chronic neck pain, without complications, back pain and lumbar pain with the respective incidence of 18%, 17,7% and 36%.[3] These three conditions negatively influence the patients' quality of life, causing substantial economic and social burdens.[4]

The chronic spinal pain is generally treated by the association of pharmacological strategies, physiotherapy and patient education, alongside other interventions, however, the treatment effects are unsatisfactory;[5] which indicates a therapeutical overview based on a biomedical model. Therefore, it is necessary to invest in studies that aim to find a holistic welfare model that is individualized and integral, as proposed by the Integrative and Complementary Practices (ICP), that aim to offer a wider view on the health disease process.[6]

In this scenario, auricular acupuncture (AA) is a group of practices of Traditional Chinese Medicine (TCM), in which specific points of the auricular pavilion are stimulated. Its application is connected to the vast innervation of the ear, composed of spinal and cranial nerves, which are capable of leading to the elevation of pain threshold in specific spots. In addition, AA is capable of promoting the discharge of endogenous endorphins and peptides in the central nervous system, which in turn have the ability to reduce nociceptive signaling in neurons, which attenuates the perception of pain.[7]

Several devices can be used in AA, such as needles, crystals, seeds, and the laser, which in turn does not have its mechanism of action entirely understood. The low-level laser therapy, with non-ionizing features, displays trophic-regenerative, anti-inflammatory and analgesic effects, besides the improvement in local microcirculation, activation of the lymphatic system, increased production of epithelial cells and fibroblasts. This device was chosen in view of the advantages over other stimulation methods, since it is painless and non-invasive.[8]

It is noted that the needles used in AA are 2.5 mm long at most, and it has been proven that lasers with wavelengths ranging between 650 and 950 nm can penetrate biological tissue at a depth of 3 mm.[9] In addition, studies suggest that the low-level laser therapy for the treatment of musculoskeletalgias has an immediate and short term positive effect if a dose of at least 3J/point is used.[10]

In auriculotherapy, laser use has been proven effective for several painful conditions, such as myofascial pain, post-operative pain and arthritis.[9,10] Its use is beneficial, especially in situations where other devices are not recommended, such as in patients who are afraid of needles, who suffer from coagulation disorders, and so on. However, for the administration of auriculotherapy through laser use, it is essential to validate standardized protocols, which allow the reproduction of effective treatment protocols.[11]

Given these considerations, this study aimed to validate an auriculotherapy protocol using low-level laser therapy for the treatment of chronic spinal pain.

METHODS

Methodological study carried out in three stages, namely: 1) development of the AA protocol with the use of low-level laser therapy to for the treatment of chronic spinal pain, based on a systematic review; 2) protocol content validation performed by judges; 3) clinical validation of the AA protocol with the use of low-level laser therapy for the treatment of chronic spinal pain.

The systematic literature review was based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA Statement).[12] The PICO (P- population; I- intervention; C- comparison; O- outcomes) strategy[13] guided the research question: What auricular acupuncture protocols are used for the treatment of chronic spinal pain in adults?

The search for the articles was conducted by three different reviewers in the period of July 2018 to February 2019, in the following databases: Medline via PUBMED, Web of Science, The Cumulative Index to Nursing and Allied Health Literature

(CINAHL), Physiotherapy Evidence Database (PEDro), Embase, Scopus, Biblioteca Virtual em Saúde (BVS), Base de Dados de Enfermagem (BDENF) and Cuban National Center for Medical Sciences Information (CUMED), LILACS via BVS.

The terms, controlled and free, defined by the Medical Subject Headings (MeSH) were combined in different ways by Boolean operators "OR" and "AND": ("Back Pain" OR "Low Back Pain" OR Sciatica OR "Chronic Pain" OR "Musculoskeletal Pain" OR "Myalgia" OR "Neck Pain" OR Lumbago OR "lumbar pain" OR "Low Back Pains" OR "Musculoskeletal Pains" OR "Muscle Pain" OR "Neck Pains" OR "Cervical Pain" OR "Cervical Pains") AND ("Auricular Acupuncture").

The eligibility criteria were: randomized clinical trials with adults (18 years of age or older); chronic pain (three months or more) in at least one of the segments of the spine (cervical, thoracic and/or lumbar) and use of auricular acupuncture, with and without laser. Studies that did not present an on-line abstract in full for analysis, those that were not located by any means (contact with the author or COMUT) and studies with pregnant women were excluded. It should be noted that the use of low-level laser therapy was not considered one of the inclusion criteria, due to the incipient number of studies regarding this device.

The data from the studies included in the review were extracted using a standardized data collection form.[14] Eligible articles were evaluated for methodological quality by the Cochrane Risk of Bias Tool. For each one of the domains of the instrument, the risk of bias is evaluated and classified as: high, uncertain or low; which allows the display of the reliability of the results of the analyzed studies.[13] This evaluation was performed by two independent reviewers and a third was consulted to resolve possible differences.

The articles analyzed were grouped into categories related to the subject of the study in question, seeking to extract information pertinent to the protocol for treatment of chronic spinal pain through auriculotherapy.

The second stage of the study was developed in the time interval between February and May 2019. Based on the recommendations of the Standards for Reporting Interventions Controlled Trials of Acupuncture (STRICTA),[15] the protocol for treatment of spinal pain with laser ear acupuncture was composed of data extracted from the first stage and complemented with information from other benchmarks.[8,16-18] It was submitted to content validation in order to verify the adequacy and relevance in relation to the attribute that it aims to achieve. For such, this trial was performed by judges, specialists in the area of the content evaluated, in order to analyze congruence of opinions.[19,20] The selection of these specialists followed the criteria established by Fehring.[20]

It should be noted that these judges were invited via telephone, totaling a group of 43 specialists in the area of the analyzed phenomenon. This was a snowball type sample, in which one volunteer suggested others. Therefore, these were contacted and after three attempts to contact the specialists, 21 professionals participated in the study. This meets the criteria for validation of the study.[19]

The specialists obtained an average of 9.5 points in the criteria established by the literature for identification of specialists.[20] Thus, it is possible to conclude that the judges were adequate to evaluate the proposed phenomenon.

As the protocol to be evaluated does not have a psychometric nature, an adaptation of Pasquali's theory was performed,[19] using only theoretical procedures in relation to relevance, structure, reliability and understanding. All the judges received the protocol provided in a form for analysis, as well as the guidelines pertinent to each item to be assessed and each question. The percentage of absolute agreement, which is given by the following formula, was used to analyze the agreement regarding the functionality and the relevance of the protocol items: % of agreement = (number of participants agreeing/total number of participants) X 100.[21] The items that obtained, in the answers, indexes of agreement between the judges greater than or equal to 80% were considered adequate.[19,20]

The third stage of the study was developed at a *Universidade Federal de Minas Gerais*, from May to July 2019, and consisted of a pilot test for clinical validation of the protocol in a group of volunteers with chronic spinal pain, identified through the Brief Pain Inventory and the nociceptive threshold.

The Brief Pain Inventory is a multidimensional instrument that evaluates the main clinical propaedeutics characteristics and the individual influence associated with pain in the last 24 hours. It measures the characteristics of pain (location, intensity and severity) and associated disability (interference with daily functions, mood, personal relationships), in addition to presenting a diagram for the location of pain, and a numerical scale from zero to 10, to grade the items according to the question: no pain (zero) and worst pain imagined (10); or, without interference (zero) and it completely interferes (10). It has a question about pharmacological or non-pharmacological methods, used for pain relief, percentage and duration of pain improvement. At the end, there are two scores, one of pain severity and another related to pain interference.[22]

The nociceptive threshold in front of the mechanical pain stimulus was evaluated by pressure algometry, which is a technique that quantifies, through the pressure on the nociceptors, the capacity of perception and painful tolerance. This physical stimulus is directly linked to weight (force) and indirectly related to the stimulated area elevated to the square; due to this the unit of measurement that expresses the results is KPa or (Kg/cm^2).[23] The pain detection threshold, induced by pressure, refers to the lowest pressure stimulus that is perceived as pain. The Kratos® Digital Algometer model DDK was used, microprocessed for tension and compression tests, with a capacity of 20 kgf and a probe tip of 2 cm in diameter.

The recruitment of volunteers was carried out through posters and social networks, with the availability of the researchers'

contacts. The population was made up of people complaining of pain in any segment of the spine who met the eligibility criteria: age group (between 18 and 80 years of age); presence of chronic pain in the spine, existing for three months or more; self-reporting of pain intensity, with score ≥ four on the Numerical Pain Intensity Scale; and availability of time for the auricular acupuncture sessions. Were excluded individuals with: infection, inflammation or injury in the auricular pavilion; who performed energy therapies up to three months before the intervention; undergoing physiotherapy treatment; in continuous use of medication for pain relief and pregnant women.

The study included a non-probabilistic sample of 20 volunteers, in which they were selected for accessibility and availability. The data collected were analyzed by the Statistical Package for the Social Sciences (SPSS), version 23.0. Abnormality was verified by Shapiro-Wilk and the paired Wilcoxon test was used, where a p-value of <0.05 was considered significant.

The research was approved by the Research Ethics Committee (CAAE n. 95158518.0.0000.5142 /Legal view n. 2.963.367).

RESULTS

In the electronic searches, 531 studies were found, of which 285 were duplicated and 233 were excluded because they did not answer the guiding question. At the end of the selection process, the review included 13 articles to summarize the analysis (Figure 1).

Figure 1 explains the results of each stage of the analysis, according to the model *PRISMA 2009 Flow Diagram*.[12]

The evaluation of the methodological quality of the articles is presented in figure 2.

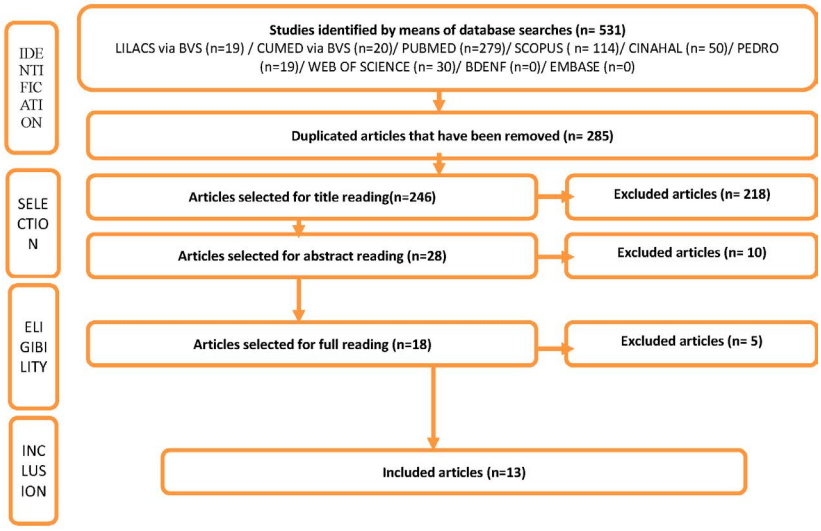

Figure 1- Selection flowchart of the systematic review articles
Source: Adapted from Liberati and collaborators.[12]

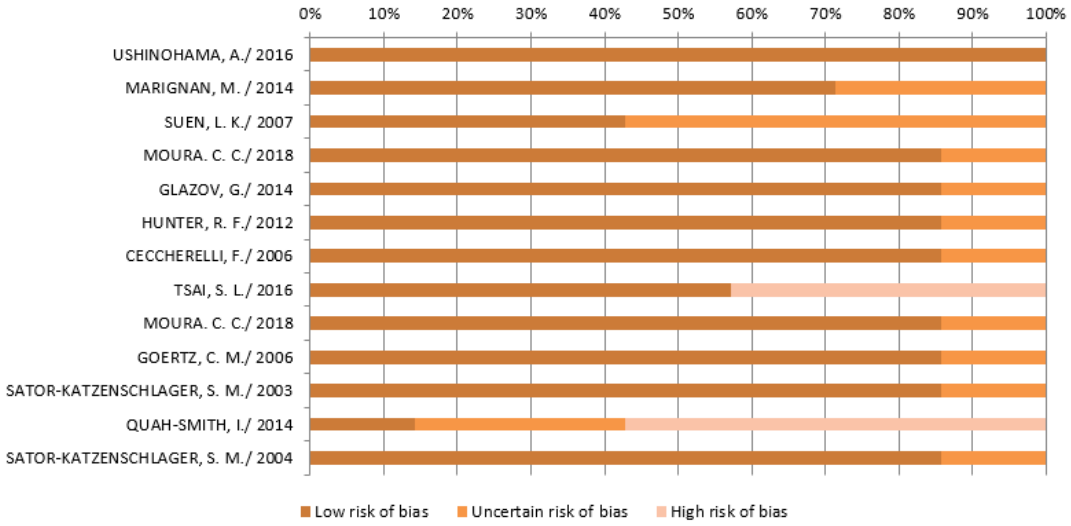

Figure 2 - Evaluation of the methodological quality of the articles included in the systematic review
Source: Adapted from Higgins; Green.[13]

Among the studies analyzed, 69% found positive results with the use of acupuncture.[11,25-28,30,31,33,34] Table 1 presents the treatment protocol of each study, consisting of the number of sessions, duration of treatment, application device, device permanence time, type of stimulus, points of application, uni or bilateral application and form of acupoints localization.

As observed in table 1, no consensus was found among the studies analyzed regarding most aspects inherent to the application

Table 1 - Treatment protocols of the articles included in the systematic review

Study identification	Pain location	Number of sessions	Treatment duration	Intervention application device	Application points	Uni/ bilateral application	Form of acupoint location	Outcome
Ushinohama *et al*, 2016[24]	Lumbar Column	1	Single	Systemic needles	*Shenmen*, analgesic point, lumbar point	Unilateral	––	Partial effect
Marignan, 2014[25]	Lumbar Column	–––––	–––	Electrical stimulator	Spinal cord; cerebellar peduncle, cerebellar formation points and vestibular nuclei (2 points)	Uni or bilateral (depending on the pain)	Electronic acupoint detector	Positive effect
Suen *et al*, 2007[26]	Lumbar Column	4	3 weeks	Magnetic spheres	Shenmen, kidney, urinary bladder, lumbosacral vertebrae, buttock, liver and spleen	Bilateral: alternated	Electronic acupoint detector and Chinese mapping	Positive effect
Moura *et al*, 2019[7]	Vertebral column	5	5 weeks	Auricular needles	Shenmen, kidney, sympathetic nervous system, energetic balance (organ and viscera), vertebrae related to the area of pain.	Bilateral: alternated	Electronic acupoint detector	Partial effect
Glazov *et al*, 2014[27]	Lumbar Column	8	8 weeks	Infrared laser diode	The acupuncture point selection was individualized for each patient.	–––	–––	Positive effect
Hunter *et al*, 2012[28]	Lumbar Column	6	6 weeks	Auricular needles	*Shenmen*, lumbar column and *Cushion*	–––	–––	Positive effect
Ceccherelli *et al*, 2006[29]	Cervical column	8	8 weeks	Systemic and auricular needles	*Shenmenn*, Lungs, cervical and Occipital column area	–––	–––	Partial effect
Tsai *et al* 2016[30]	Vertebral column	1	Single	Gold spheres and auricular needles	Omega 2, *Shenmen*, Backson 0, Thalamus, cingulate gyrus	Unilateral	–––––	Positive effect
Moura *et al*, 2018[31]	Vertebral column	5	5 weeks	Auricular needles	*Shenmen*, Kidney, sympathetic nervous system, and energetic balance (one organ and one viscera) and vertebrae related to the location of pain	Bilateral: alternated	Electronic acupoint detector	Positive effect
Goertz *et al*, 2006[32]	Unspecific painful syndromes, including the vertebral column	1	Single	Auricular needles	Cingulate gyrus and thalamic nuclei	Bilateral	–––	Partial effect
Sator-Katzenschlager *et al*, 2003[34]	Cervical Column	6	6 weeks	Systemic needles connected to the electrostimulation device	*Shenmen*, *cervical column and Cushion*	Bilateral: alternated	Electronic acupoint detector	Positive effect
Quah-Smith, 2014[11]	Vertebral column	4	4 weeks	NextLaser	Adaptation of Marignan's posturology protocol, vestibular nuclei, point zero, lumbar and cervical vertebrae and related muscles	Bilateral	–––	Positive effect
Sator-Katzenschlager *et al*, 2004[33]	Lumbar Column	6	6 weeks	Systemic needles connected to the electrostimulation	*Shenmen*, lumbar column and *Cushion*	Bilateral: alternated	Electronic acupoint detector	Positive effect

of auricular acupuncture for spinal pain. Therefore, for the development of the treatment protocol, regarding the number of sessions and duration period, the simple average of these items was observed in the studies. Regarding the frequency of treatment, one session per week was suggested, in line with the majority (85%) of the articles. The protocol followed the bilateral application method, with alternation of the auricular pavilion, as it was performed in 54% of the studies.

Studies using a needle (54%) as a device for the application of auriculotherapy obtained 23% positive effects in the treatment, while the protocols using a laser (38%) had 100% positive effects (Table 1). Thus, the laser was the device selected to perform the application of the intervention.

Regarding the points used (Table 1), there is only consensus about the Shenmen, which was pointed out in 77% of the studies; for the other points there was no compliance. This fact justified the present study to choose the acupoints, according to the references that guide the practice.[8,16-18]

Thus, the protocol for treatment of chronic pain in the spine with auricular acupuncture was concluded as follows: a weekly session of acupuncture with low-level laser therapy, for five weeks; with alternation of the auricular pavilion between the sessions and with the following acupuncture: Shenmen, Kidney, Sympathetic, Urinary Bladder, Liver, Subcortex, Cervical, Thoracic and/or Lumbar vertebrae, depending on the pain location. The use of DCM® branded infrared low-level 808 nm laser (Therapy EC) was determined. This equipment has a useful emission power of 100mW. A dosage of 4J per stimulated point was used.[8] Regarding the application time per point, the equipment automatically calculates it according to the dosage used, generating a time of 40 seconds per point.

To evaluate the content determined in the protocol, judges were invited, who had on average six and a half years of clinical practice in acupuncture. Regarding their qualifications, 9 (43%) were doctors, 5 (24%) were specialists, 4 (19%) were masters and specialists, and 3 (14%) were masters.

The final analysis, of the level of agreement of the content, generated the approval of all the items. There was 100% agreement among the interobservers for the points determined for auriculotherapy application, 95% for laser configuration and use of the locator pen for confirmation of the points, and only the item "Asepsis of the hands of the interventionist with alcohol 70%" received 85% agreement among the specialists.

Regarding the clinical evaluation of the protocol developed for the treatment of chronic spinal pain, using laser auriculotherapy, the study had the participation of 20 volunteers: 13 (65%) were female and 7 (35%) were male; with ages between 20 and 65; marital status, 12 (60%) were single, 6 (30%) were married and 2 (10%) were divorced; occupational status, 12 (60%) were students, 4 (20%) were dependent on aid illness, 2 (10%) had a job, and one (5%) was unemployed and one (5%) was retired.

Regarding the pain profile, 11 (55%) reported pain in the lumbar column, 10 (50%) in the cervical segment, and 2 (10%) in the thoracic portion. It is noteworthy that some volunteers reported pain in more than one spine segment, in addition, two others (10%) presented pain in the spine as a whole.

Regarding the evaluation of the average and pain threshold of the study volunteers, after laser auriculotherapy, showed significant statistical improvement was observed, in which the mean severity in the pre-intervention was 7.20 (SD: 1.47) and in the post-intervention it was 4.75 (SD: 1.66), with p = 0.000. With regard to the tolerance threshold for pain assessment, this was 4.63 (SD: 1.73) in the pre-intervention period, while in the post-intervention it went to 5.19 (SD 1.35), with p = 0.033.

The pain tolerance threshold, evaluated by pressure algometry, showed statistically significant improvement, especially in the lumbar segment (Table 2).

Table 2 - Evaluation of the pain threshold of study volunteers, before and after laser auriculotherapy, at the points analyzed by algometry, *Minas Gerais* (n= 20).

Region		Average (Standard Deviation)		P value
		Pre-Intervention	Post-Intervention	
Occipital	Right	4.44 (1.61)	4.33 (1.44)	0.658
	Left	3.73 (1.65)	3.28 (1.68)	0.313
Cervical Region	C5	4.98 (2.47)	4.70 (1.98)	0.695
	C6	4.84 (2.48)	5.19 (1.58)	0.263
Trapezium	Right	3.72 (1.69)	3.85 (1.29)	0.629
	Left	3.60 (2.03)	4.24 (1.89)	0.113
Inferior angle Scapula	Right	4.35 (2.19)	4.77 (2.00)	0.167
	Left	4.75 (2.57)	5.40 (2.00)	0.263
Thoracic (T8)		5.64 (2.23)	6.38 (2.11)	0.108
Posterior superior iliac spine	Right	4.55 (1.92)	5.52 (1.58)	0.020
	Left	5.24 (1. 82)	5.92 (2.20)	0.170
Lumbar	L4	4.92 (2.58)	6.30 (2.76)	0.020
	L5	5.42 (2.90)	6.27 (2.28)	0.033
Gluteal region	Right	4.60 (1. 99)	5.89 (2.20)	0.001
	Left	4.74 (1.73)	5.84 (2.32)	0.003

* *Wilcoxon's* paired test, p<0,05

Regarding the impact of pain on the volunteers' lives, in the last 24 hours, i.e., the disability associated with daily activities, mood, personal relationships, work and ability to appreciate life, improvements were observed, with statistical significance, in all aspects evaluated, according to table 3.

Table 3 - Evaluation of the disability associated with daily activities, in mood and personal relationships caused by pain in the last 24 hours of study volunteers' lives, before and after laser auriculotherapy, *Minas Gerais* (n= 20).

Pain interference in the last 24 hours	Average (Standard Deviation)		P value*
	Pre-Intervention	Post-Intervention	
In general activity	7.05 (2.78)	3.90 (3.323)	0.001
In the mood	6.55 (3.77)	3.45 (4.242)	0.170
In the ability to walk	5.90 (3.52)	2.75 (3.22)	0.005
At work	7.40 (2.54)	3.00 (3.00)	0.001
In the relationship with people	4.60 (3.80)	2.25 (3.32)	0.044
In sleep	5.65 (3.58)	3.05 (3.45)	0.005
In the ability to enjoy life	5.40 (3.102)	3.20 (3.07)	0.013

* *Wilcoxon's* paired test, p<0,05

DISCUSSION

The systematic review of the literature found a positive effect of acupuncture on pain relief in 69% of the studies analyzed and in 100% when applied with laser; which corroborates the effectiveness of the technique as a treatment method for spinal pain.[25] From these results, it became feasible to develop a protocol for the treatment of spinal pain with laser auricular acupuncture, which also included the recommendations of STRICTA in order to maintain the focus on its scientific and clinical reproduction.

Despite the need for standardized treatment protocols to establish the scientific rigor of a study, it was possible to observe the lack of consensus among the authors investigated in this review, regarding the different aspects of the detailing of the intervention used. This difficulty may be linked to one of the principles of TCM regarding the individuality of the therapy. Therefore, when AA is strictly based on the precepts of TCM, the variation in ear points, session numbers and devices may be justified.[7]

Only the determination of the Shenmen point was a consensus among the studies, as it is considered essential for pain treatment. This point is also called "door of the spirit or mind", presenting sedative and analgesic functions through the release of endorphins, anti-infammatory, antipyretic.[24]

To determine the best ways to treat patients with chronic pain, it is necessary first to scientifically demonstrate the efficacy of the intervention and then apply this evidence in clinical practice.[31] Therefore, it is essential to establish methodologically consistent protocols, with a precise and well-founded description of the criteria established for the selection of auricular points, as well as the justification for the number of sessions and stimulation devices selected.

After the theoretical development of the protocol, it is important that it be submitted to a thorough analysis of its content by specialists in the investigation phenomenon. The selection of these professionals is then, the core of this methodological approach, thus, it is of fundamental importance to the adequate choice of criteria for the selection of specialists, so that there is no interference in the reliability of the results obtained.[35]Thus, this study, having judges with proven experience in auricular acupuncture and also pain phenomenon scholars, in both practical and theoretical fields, allowed greater rigor in the analysis of the proposed content of the intervention protocol, which in turn obtained a level of agreement above 80% in all items proposed. Therefore, it is assumed that it is adequate for the treatment of chronic spinal pain.[19]

The clinical evaluation of the treatment protocol, by means of acupuncture with low-level laser therapy for spinal pain demonstrated efficacy in reducing the severity of pain and its impact on daily life activities, in the same way that it improved the pain threshold of study participants. This corroborates the results observed in a meta-analysis in which the auricular therapy was effective in reducing the intensity of pain, especially that which affects the lumbar region, as observed in this study in relation to the tolerance threshold.[37]

In the present study, statistically significant reductions were also found for the impact of pain on daily life activities; mood; walking ability; work; relationships with other people; sleep and appreciation of life, between the initial and final evaluations. These results are in line with those found in a study,[7] when measuring these variables through BPI, finding a statistically significant reduction of pain interference in daily activities was found after treatment with acupuncture.

Therefore, the acupuncture protocol with laser has proven to be effective for the treatment of spinal pain in the participants of this study, allowing an evaluation of its suitability as a therapy. Certainly, it is essential for there to be other studies that carefully evaluate the application processes of this protocol, on top of long-term follow-up studies with people with pain.

CONCLUSION

The auricular acupuncture, performed with infrared low-level laser, in five sessions, once a week, with alternation of the auricular pavilion at each session, in the points: Shenmen, Kidney, Sympathetic Nervous System, Urinary Bladder, Liver, Subcortex, Cervical, Thoracic and/or Lumbar vertebrae, depending on the location of pain; according to the precepts of TCM, has been proven to be able to effectively treat chronic pain in the spine.

Therefore, it is expected that the present study can contribute with scientific evidence in order to favor the Nursing protagonism in the implementation of auricular acupuncture as an intervention device for the treatment chronic pain, which should be easily administered, fast, inexpensive, and without side effects. Furthermore, it should benefit a larger number of people, contributing to the prevention, protection, promotion, and recovery of the health and quality of life of those affected with musculoskeletal disorders.

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